Dated, Washington, DC, November 29, 1989.

By direction of the Board.

John C. Truesdale,

Executive Secretary, National Labor Relations Board.

[FR Doc. 89-28282 Filed 11-29-89; 11:47 am]

BILLING CODE 7445-01-M

Corrections

Federal Register
Vol. 54, No. 230
Friday, December 1, 1989

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185 and 186

[OPP-300202; FRL-3643-1]

Daminozide; Revocation and Amendment of Tolerances and Food Additive Regulations

Correction

In proposed rule document 89-21162 beginning on page 37278 in the issue of Thursday, September 7, 1989, make the following corrections:

1. On page 37278, in the first column, under **SUMMARY**, in the fourth line, "regulatory" should read "regulator".

2. On page 37279, in the second column, in the table, in the third column, in the seventh line from the bottom, "0.2" should read "2.0".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 160

[OPP-300165A; FRL-3518-2]

RIN 2070-AB68

Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards

Correction

In rule document 89-19087 beginning on page 34052 in the issue of Thursday, August 17, 1989, make the following correction:

§ 160.31 [Corrected]

On page 34069, in the first column, in section heading § 160.31, "facility" was mispelled.

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 795 and 799

[OPTS-42100B; FRL-3627-4]

Tributyl Phosphate; Final Test Rule

Correction

In rule document 89-18850 beginning on page 33400 in the issue of Monday, August 14, 1989, make the following corrections:

1. On page 33400, in the second column, under *A. Exposure*, in the 16th line, delete the commas after "Sloane" and "Inc."

2. On page 33401, in the first column, under *B. Testing*, in the second paragraph, in the third line, "teset" should read "test".

3. On the same page, in the second column, in the first complete paragraph, in the last line, "absoprption" should read " absorption".

4. On the same page, in the same column, under " 3. *Oncogenicity*", in the eighth line, "efforts" should read "effects".

5. On the same page, in the third column, under "7. *Neurotoxicity*", in the seventh line, "review" was mispelled.

6. On page 33403, in the third column, in the second line, "for" should read "are".

7. On page 33406, in the first column, in the sixth line, "rats" should read "rat".

8. On the same page, in the third column, in the sixth line, "of" should read "to".

9. On page 33408, in the first column, in the second paragraph, in the 10th line from the bottom, insert "the" after "in".

10. On the same page, in the same column, under *D. Persons Required to Test*, in the third line, "proceeding" should read "processing".

11. On the same page, in the second column, in the first complete paragraph, in the eighth line, "to" should read "or".

12. On the same page, in the same column, in the fourth complete paragraph, in the first line, delete, "rule to this subject", and add "subject to this rule".

§ 795.228 [Corrected]

13. On page 33411, in the first column, in § 795.228(a), in the first line the second "purpose" should read "purposes".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42099A; FRL-3645-8]

Methyl Ethyl Ketoxime; Final Test Rule

Correction

In rule document 89-21497 beginning on page 37799 in the issue of Wednesday, September 13, 1989, make the following corrections:

1. On page 37800, in the first column, under *A. Route of Administration*, in the second paragraph, in the fourth line from the bottom remove the "l" after "reproductive".

2. On page 37801, in the first column, in the third complete paragraph, in the fourth line from the bottom, "sex-relinked" should read "sex-linked".

3. On the same page, in the second column, in the first paragraph, in the 12th line, "tests" should read "testes".

4. On the same page, in the same column, in the same paragraph, in the fifth line from the bottom, "not" should be removed.

5. On the same page, in the third column, in the third complete paragraph, in the first line, "commented" should read "comments".

6. On the same page, in the same column, in the same paragraph, in the third line, "tisses" should read "tissues".

7. On page 37802, in the second column, in the second complete paragraph, in the fourth line from the bottom, "approoach" should read "approach".

8. On the same page, in the third column, in the second complete paragraph, in the last line, "mutagenci" should read "mutagenic".

9. On the same page, in the same column, in the third complete paragraph, in the third line, "tests" should read "testes".

10. On page 37803, in the third column, under *B. Required Testing and Test Standards*, in the second line, "preamble" was mispelled.

11. On the same page, in the table at the bottom, in the third column, "Reporting deadline for final report", in

the sixth line, "18/17" should read "14/17".

12. On page 37804, in the second column, under *C. Test Substance*, in the third line from the bottom, "teting" should read "testing".

13. On the same page, in the third column, in the third line, "Processor" should read "Processors"

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-62079; FRL 3638-2]

Asbestos-Containing Materials in Schools; EPA Approved Courses and Accredited Laboratories Under the Asbestos Hazard Emergency Response Act (AHERA)

Correction

In notice document 89-20575 beginning on page 36166 in the issue of Thursday, August 31, 1989, make the following correction:

On page 36168, in the second column, in the first complete paragraph, in the fourth line from the bottom, "Eighteen" should read "Fifteen".

BILLING CODE 1505-01-D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 88-330; RM-6210, RM-6304, RM-6473]

Radio Broadcasting Services; Gadsden, Holly Pond, and Attalla, AL

Correction

Rule document 89-26639 beginning on page 47361 in the issue of Tuesday, November 14, 1989, was published incorrectly as a proposed rule in the rule section.

BILLING CODE 1505-01-D

Federal Register

Friday
December 1, 1989

Part II

Environmental Protection Agency

40 CFR Part 35

Technical Assistance Grants to Groups at National Priorities List Sites; Amendments to Interim Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 35

[FRL-3555-9]

Technical Assistance Grants to Groups at National Priorities List Sites

AGENCY: Environmental Protection Agency (EPA).

ACTION: Amendments to the interim final rule with request for comments.

SUMMARY: Pursuant to section 117(e) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, 42 U.S.C. 9617(e), the Environmental Protection Agency (EPA or the Agency published in the **Federal Register** on March 24, 1988 (53 FR 9736) an Interim Final Rule (IFR) for the Technical Assistance Grant Program. The IFR detailed the specific requirements for citizens' group to obtain technical assistance grants. EPA stated that publication of the rule as an IFR with an immediate effective date allowed the Agency to begin accepting applications from citizens' groups for financial assistance without delay, while simultaneously accepting comments on, and developing the Final Rule.

Today EPA is publishing amendments to the IFR regarding the Technical Assistance Grant Program in order to foster greater participation of citizens' groups in the grant program. The Agency has benefitted from its early experience with the grant program and the public comments on the IFR and has decided to make immediate changes to the program. Thus, EPA has determined that publication of amendments to the IFR at this time will help streamline the grant award process while allowing the Agency the opportunity to continue to evaluate the Technical Assistance Grant Program, to accept public comments on the amendments to the IFR, and to proceed with the development of the Final Rule.

DATES: *Effective Date:* December 1, 1989.

Comments: Written comments must be submitted on or before January 30, 1990.

ADDRESSES: Written comments must be submitted to: Superfund Docket Clerk, Office of Emergency and Remedial Response (OS-240), Room M 2447, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Comments on today's amendments to the IFR must identify the regulatory docket as follows: "Docket CERCLA 117(e), Technical Assistance Grant Regulation."

Docket: Copies of materials relevant to this rulemaking are contained in the Superfund docket located on the second floor of the Mall (Room M 2447) at the U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The docket is available for inspection by appointment only between the hours of 9 a.m. and 4 p.m. Monday through Friday, excluding Federal holidays. The docket phone number is (202) 382-3046. As provided in 40 CFR part 2, a reasonable fee may charged for copying services.

FOR FURTHER INFORMATION CONTACT: Murray Newton, Office of Emergency and Remedial Response, OS-220, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 at (202) 382-2460 or the RCRA/Superfund Hotline from 8:30 a.m. to 7:30 p.m., Monday-Friday, toll free at 1-(800)-424-9346 or in Washington, DC at 382-3000.

SUPPLEMENTARY INFORMATION: The contents of today's preamble are listed in the following outline:

I. Introduction

A. Authority

These amendments to the IFR are issued under the authority of section 117(e) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended, hereinafter cited as CERCLA, 42 U.S.C. 9617(e). Section 117(e) authorizes the President to make available technical assistance grants of up to $50,000 to groups of individuals to obtain assistance in interpreting information related to Superfund sites. Section 117(e) requires the President to promulgate rules for issuing these grants before processing any grant applications. Executive Order No. 12580 delegated to EPA the authority to implement section 117(e) in consultation with the Attorney General.

B. Background of the Rulemaking

As background to this rulemaking, pursuant to section 117(e), EPA published in the June 10, 1987 **Federal Register** (52 FR 22244) an Advance Notice of Rulemaking (ANRM) which discussed and solicited comments on several issues and various approaches that EPA was considering for accepting and evaluating applications, and for awarding and managing technical assistance grants. EPA stated that it would consider those comments in formulating the IFR.

After careful consideration of the public comments on the ANRM, EPA published the IFR in the March 24, 1988 **Federal Register**. The IFR detailed the specific requirements for obtaining technical assistance grants. The IFR enabled EPA to issue grants immediately while continuing to receive comments that the Agency stated that it would consider in the development of the Final Rule.

The Agency has benefitted from its early experience with the Technical Assistance Grant Program and has determined that certain changes need to be made immediately while the Final Rule is being developed. The Agency is issuing today amendments to the IFR to encourage more citizens' groups to participate in the Technical Assistance Grant Program and to elicit further input by the public into the development of the Final Rule.

A total of 42 comments were received in response to the IFR. Approximately two-thirds of the commenters stated that the regulations made the Technical Assistance Grant Program overly restrictive. This view was also reflected in two letters from members of Congress to the EPA Administrator: one dated September 15, 1988 signed by 10 Senators and another letter dated June 10, 1988 signed by 49 Representatives. These letters have been submitted to the Superfund Docket and are now part of the official record for the development of the Final Rule. The letter from the 49 Representatives expressed the view that the IFR, as written, would "significantly impede the ability of citizens to receive grants and use the funds in ways consistent with the intent of Congress." The letter from the 10 Senators stated that, "We believe that most 'Superfund Communities' will find the program unnecessarily difficult to use unless major changes are made to these regulations. The current regulations: (1) Discourage groups from applying; (2) unnecessarily complicate the already difficult task of obtaining a technical

advisor(s); and (3) excessively restrict the uses of the Fund."

Moreover, since publication of the IFR, the Agency has learned through experience implementing the program that certain requirements of the IFR tend to dissuade citizens' groups from applying for technical assistance grants. This experience supports the statements made by the formal commenters that the Technical Assistance Grant Program is, in their view, overly restrictive and, therefore, citizens' groups are discouraged from submitting applications.

Therefore, as a result of EPA's internal review of the program, public comments, and program experience, the Agency has concluded that certain immediate changes to the IFR need to be made. The Agency believes that these changes will promote greater participation of citizens' groups in the grant program and facilitate the use of technical assistance grants at Superfund sites. Today EPA is amending the following sections of the IFR with this rule: (a) the 35 percent match required of recipient groups as discussed in § 35.4085(a); (b) the 15 percent cap on administrative costs as set forth in § 35.4085(e); and (c) the requirement for incorporation as discussed in § 35.4020.

It should also be noted that elsewhere in the March 24, 1988 **Federal Register** (53 FR 9753), EPA published an Advance Notice of Rulemaking (ANRM) to solicit comments from the public on a proposal to provide technical assistance grant applications and/or recipients with the services of an Administrative Services Contractor (ASC). It was stated that these services could include both assistance in preparing grant applications and the procurement of technical assistance, and contract management.

In light of the negative public comments, the Agency has decided not to pursue the ASC concept further. As an assistance alternative, the Agency has provided additional personnel, through its Senior Environmental Employees (SEE) Program, to assist the EPA Regional Offices in administering the Technical Assistance Grant Program. With the addition of SEE Program employees, the EPA Regional Offices are able to provide more assistance to citizens' groups than they would otherwise.

II. Responses to Major Public Comments on Issues Being Reconsidered in the Amendments to the IFR

The Agency received comments from a wide range of interested parties, including State and Federal legislators, lawyers, consultants, academicians, national and State environmental groups, State agencies, political subdivisions of a State, community groups and industry. The issues under consideration in today's rulemaking that were addressed by these commenters and EPA's responses to them are described below.

A. The 35 Percent Matching Funds Requirement

Section 117(e)(2) of CERCLA states that "[e]ach grant recipient shall be required, as a condition of the grant, to contribute at least 20 percent of the total costs of the technical assistance for which such grant is made. The President may waive the 20 percent contribution requirement if the grant recipient demonstrates financial need and such waiver is necessary to facilitate public participation in the selection of remedial action at the facility."

The Agency stated at 53 FR 9743 that this language clearly expressed the intent of Congress that the affected community's ability to pay should affect the size of the match for the technical assistance grant. In the IFR, EPA set the matching funds requirement at a figure of 35 percent of total project costs. EPA invited comments on how to develop a workable system for determining the matching share based on financial need and other factors for inclusion in the Final Rule.

However, EPA believes that the 35 percent matching funds requirement has been an impediment to citizens' groups applying for technical assistance grants and that a reduction in the matching funds requirement will encourage formerly reluctant groups to apply. The Agency has arrived at this conclusion based on the following.

Every commenter who addressed this issue stated that the 35 percent matching funds requirement is excessive. Several recommended that it be set at 20 percent; while others suggested that even 20 percent would be difficult for citizens' groups to raise and offered variations. Some suggested a lenient waiver policy instead.

Several members of Congress expressed the same concerns. For example, the September 15, 1988, letter of the 10 Senators stated that "[T]he 35 percent match required of recipient groups is excessive. The figure must be lowered to 20 percent, which is the minimum level specified in the law."

EPA's experience with the program, public comments, and comments from EPA Regional personnel indicate that the 35 percent matching funds requirement has served as an impediment to citizens' groups applying for a technical assistance grant, especially those groups with few financial resources—the very groups that the grant program was designed to help. Even citizens' groups from more affluent communities have had trouble raising the 35 percent "match" of the total project costs. For example, for a $50,000 grant, which would amount to 65 percent of the total project funds, citizens' groups were required to provide the remaining $26,923 ($50,000 of Federal funds represents 65 percent of the total project funds—or $76,923—which would require a 35 percent "match" of $26,923 from the grant recipient in cash or in-kind contributions).

In today's amendments to the IFR, the Agency has determined that each grant recipient must contribute 20 percent, instead of 35 percent, of the total project costs. For example, with a $50,000 grant, which would amount to 80 percent of the total project funds, citizens' groups will be required to provide the remaining $12,500. ($50,000 of Federal funds represents 80 percent of the total project funds—or $62,500—which would require a 20 percent "match" of $12,500 from the grant recipient in cash or in-kind contributions.)

B. The 15 Percent Cap on Administrative Costs

In formulating the IFR, the Agency was concerned with the purposes for which technical assistance grant funds would be used. The Agency, for example, stated in the Preamble to the IFR at 53 FR 9743 that "In order to ensure the best use of limited technical assistance grant funds, costs of administering the grant are allowable to the extent that they do not exceed 15 percent of total project costs."

The Agency continues to be concerned with the uses of technical assistance grant funds but has determined, based upon experience and public comment, that most of the eligible goods and services for in-kind contributions fall within the administrative category. Citizens' groups tend to be able to meet the administrative portion of the matching funds requirement but have had difficulty in meeting the non-administrative portion. EPA has, therefore, concluded that the elimination of the 15 percent cap on administrative costs will enable citizens' groups to meet their matching funds requirement without having to ask for a waiver of the remaining 5 percent. The Agency believes that this will encourage greater participation of citizens' groups in the Technical Assistance Grant Program.

C. Incorporation

In formulating the IFR, the Agency determined that each grant recipient must be incorporated as a non-profit organization for the purpose of addressing the Superfund site for which the grant was provided in order to receive a technical assistance grant. In the Preamble to the IFR at 53 FR 9740, the Agency stated that EPA's analysis concluded that incorporation offers advantages to both recipients and EPA, and does so at relatively little cost to both.

As set forth at § 35.4020(b) of the IFR, the citizens' group receiving a technical assistance grant must be a non-profit corporation that includes all the individuals and groups that joined in applying for the grant and was incorporated for the purpose of addressing the Superfund site for which the grant was to be awarded. At the time of the award, a recipient must either be incorporated or demonstrate that it has taken all necessary and appropriate actions to incorporate. Thus, applicants are not required to be incorporated at the time that the application is submitted; only recipients of technical assistance grant awards must be incorporated. However, the recipient must submit proof that the group had been incorporated by the State no later than the time of the group's first request for reimbursement for costs incurred.

The Agency has considered further those situations where the existing regulation requires an incorporated group to reincorporate for the purposes of the Technical Assistance Grant Program. Several commenters suggested this requirement could be overly restrictive in some circumstances.

The Agency has determined that in situations where a group is already incorporated with a broader mandate than addressing the site and has a substantial history of involvement at the site, the group need not reincorporate for the purpose of addressing the problems at a Superfund site. The IFR is, therefore, amended to permit a grant to an incorporated group having a history of substantial involvement at the site and if the corporation includes all the individuals and groups that joined in applying for the grant.

D. Language Clarification

Section 35.4035 of the IFR set out the evaluation criteria EPA will use in reviewing tag applications. One of the five criteria is representation of the groups and individuals affected by the site. Commenters have asked for clarification of what the Agency considers to be a "representative" group.

The Agency's intent is to make technical assistance available to a broad range of affected individuals in the community. This would include residents, other property owners, recreational and environmental interest groups, and any others (except, of course, potentially responsible parties, who are ineligible under § 35.4030) who believe their health, property values, recreation, local ecological balance, or aesthetic appreciation of their community to be diminished by the site. EPA believes that groups promoting a single interest (e.g., economic, environmental, or societal) to the exclusion of other interests do not represent the full range of community interests. Such groups exclude community members who are legitimately affected by the site, but who do not necessarily support the views of mission of the interest group. Accordingly, EPA will give preference to groups representing a diversity of community interests which require objective information from independent advisors to understand how the site and the cleanup activities affect their well-being.

The Agency stated in the Preamble to the IFR at 53 FR 9743 that "[C]osts associated with disputes with the Agency or challenges to final Agency decisions (e.g., Records of Decisions) are not allowable since this also would be inconsistent with Congressional intent of 'interpreting information'."

The IFR at § 35.4055(a)(7) prohibits the use of technical assistance grant funds for "conducting disputes with the Agency." This phrasing has been misconstrued as requiring technical assistance grant recipients to agree with EPA on every issue and decision. In fact, the provision is not meant to inhibit citizens from disagreeing with the Agency on any issue. It does mean, however, that if a citizens' group is in a dispute with the Agency as to whether it has managed its grant properly, technical assistance grant funds may not be used during the formal dispute resolution process outlined in 40 CFR Part 30, Subpart L. For example, should the Agency determine that a certain cost for which the citizens' group seeks reimbursement is an unallowable cost under the technical assistance grant agreement, the citizens' group could not use technical assistance grant funds to cover the preparation or processing of costs to appeal that decision under subpart L of the Agency's grant regulations.

The language regarding "challenges to final Agency decisions" nevertheless apparently has been misinterpreted. The IFR at § 35.4055(a)(7) prohibits the use of technical assistance grant funds to reopen final Agency decisions. Once a Record of Decision (ROD) is signed, for example or a design plan is final, grant funds cannot ordinarily be used to challenge that decision or plan, but must be spent on the next phase of the process. By limiting the use of technical assistance grant funds in this manner, however, the Agency is not seeking to constrain technical assistance grant recipients from expressing their disagreements with or opposition to any Agency action or decision. On the contrary, the Agency recognizes the importance of informed comment from citizens' groups and the need for citizens to be well-informed at the sites. However, the process of cleaning up a Superfund site requires detailed technical studies of site conditions and wastes, analysis of methods, and techniques for remediation over an extended period of time. The Records of Decision are culminations of these efforts and revisiting settled issues and past decisions is not a cost effective use of limited technical assistance grant funds for citizens' groups. However, if the Agency or a court officially reopens a Record of Decision, or formally requests comments on it, then the grant money can be used to review appropriate documents.

The Agency stated at § 35.4090(b) of the IFR that "Waivers of the matching funds requirement will only be granted in exceptional cases." Some readers have mistakenly understood this to be an independent requirement for a waiver, erroneously believing that they had to meet this standard in addition to the three criteria listed in § 35.4090(b). In fact, waivers can be granted whenever the three requirements at § 35.4090(b) are met. The Agency has concluded that the reference to "exceptional cases" should be eliminated and has amended § 35.4095(b) accordingly.

III. Existing Grants

Citizen groups that have received technical assistance grants with a matching funds requirement of greater than 20 percent or an administrative cap of 15 percent may seek an amendment of their grants. Those citizens' groups should contact the appropriate EPA Regional Office.

IV. Regulatory Analyses

A. Regulatory Impact Analysis

Executive Order No. 12291 requires that regulations be classified as "major" or "non-major" for purposes of review

by the Office of Management and Budget (OMB). According to Executive Order No. 12291, "major" rules are regulations that are likely to result in:

(1) An annual adverse (cost) effect on the economy of $100 million or more; or
(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government, or geographical regions; or
(3) Significant adverse effects on the competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The IFR for the Technical Assistance Grant Program is a "non-major" rule, therefore these amendments are considered "non-major." The amendments would have no significant annual adverse effect on the economy of $100 million or more; or a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 requires that Agencies evaluate the effects of a rule for three types of small entities:

(1) Small businesses (as defined in the Small Business Administration regulations);
(2) Small organizations (independently owned, nondominant in their field, non-profit); and
(3) Small government jurisdictions (serving communities of less than 5,000 people).

EPA has consistently considered the interests of small non-profit entities in designing the Technical Assistance Grant Program. Today EPA is amending the IFR to encourage small entities to apply. And, for some applicants the Agency may waive the matching funds requirement.

Since today's rule is not expected to have a significant impact on small non-profit entities, EPA certifies that no Regulatory Flexibility Analysis is necessary.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget under the provisions of the *Paperwork Reduction Act*, U.S.C. 3501 *et seq.* and have been assigned OMB control number 2030–0020 for activities involving the grant application process, and 2050–0083 for activities specifically related to the rule.

Public reporting burden for this collection of information is estimated to average 8 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden the Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC, 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20503, marked "Attention, Desk Officer for EPA."

V. Supporting Information

List of Subjects in 40 CFR Part 35

Grant programs—environmental protection, Matching funds, Public involvement, Reporting and recordkeeping requirements, Hazardous wastes, Superfund.

Dated: November 27, 1989.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, Title 40, Chapter I, of the Code of Federal Regulations is amended as follows:

PART 35—[AMENDED]

Subpart M—Grants for Technical Assistance

1. The authority citation for subpart M continues to read as follows:

Authority: 42 U.S.C. 9617(e); sec. 9(g), E.O. 12580.

2. Section 35.4020 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 35.4020 Responsibility requirements.

* * * * *

(b) Each recipient of a technical assistance grant must be incorporated as a non-profit organization for the purpose of addressing the Superfund site for which the grant is provided in order to receive a grant, except as provided in paragraph (c) of this section. At the time of award, a recipient must either be incorporated or must demonstrate to EPA that the group has filed the necessary documents for incorporation with the appropriate State agency. No later than the time of the first request for reimbursement for costs incurred, a recipient must submit proof that the group has been incorporated by the State.

(c) Unless a consolidation agreement makes site-specific incorporation necessary, a previously incorporated group that includes all the individuals and groups that joined in applying for the technical assistance grant shall not be required to incorporate for the specific purpose of representing affected individuals at the site provided that the group can demonstrate that it has a substantial history of involvement at the site.

3. Section 35.4030 is amended by revising paragraph (a)(2) to read as follows:

§ 35.4030 Ineligible applicants.

(a) * * *

(2) Corporations that are not incorporated for the specific purpose of representing affected individuals at the site except as provided in § 35.4020(c);

* * * * *

4. Section 35.4055 is amended by revising paragraphs (a)(1) and (a)(7) to read as follows:

§ 35.4055 Ineligible activities.

(a) * * *

(1) Litigation or underwriting legal actions such as paying for attorney fees or paying for the time of the technical advisor to assist an attorney in preparing a legal action or preparing for and serving as an expert witness at any legal proceeding regarding or affecting the site;

* * * * *

(7) Reopening final Agency decisions such as the Records of Decision or conducting disputes with the Agency in accordance with its dispute resolution procedures set forth at 40 CFR Part 30, Subpart L.

5. Section 35.4085 is amended by revising paragraph (a) introductory text and removing paragraph (e) to read as follows:

§ 35.4085 Grant limitations.

* * * * *

(a) The recipient must contribute 20 percent of the total costs of the technical assistance grant project, except as provided in § 35.4095(b) of this regulation.

* * * * *

6. Section 35.4090 is amended by revising paragraph (b) introductory text to read as follows:

§ 35.4090 Waivers.

* * * * *

(b) Waivers of the matching funds requirement will be granted only when it is established that the grant recipient cannot meet the matching funds requirement. The Agency may waive all or part of the recipient's matching funds requirement only after a finding by the Agency that:

* * * * *

[FR Doc. 89-28143 Filed 11-30-89; 8:45 am]
BILLING CODE 6560-50-M

federal register

Friday
December 1, 1989

Part III

Department of Transportation

Office of the Secretary

49 CFR Part 40

Procedures for Transportation Workplace Drug Testing Programs; Final Rule and Notice of Conference

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket No. 45928; Notice No. 2]

RIN 2105-AB42

Procedures for Transportation Workplace Drug Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department of Transportation is adopting a final rule concerning testing procedures applicable to drug testing programs the Department requires in six transportation industries. The final rule incorporates modifications in response to comments on the Department's November 21, 1988, interim final rule on the same subject.

EFFECTIVE DATES: This rule is effective January 2, 1990, except that § 40.31(d) is effective May 30, 1990 for employers with fewer than 2000 covered employees. Compliance with all portions of this rule is authorized immediately.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 400 7th Street, SW., Room 10424, Washington, DC 20590, (202-366-9306).

SUPPLEMENTARY INFORMATION: On November 21, 1988 (53 FR 47002), the Department published an interim final rule establishing drug testing procedures applicable to drug testing for transportation employees under six Department of Transportation regulations. These six regulations were published on that same date by the Federal Aviation Administration, Federal Highway Administration, Federal Railroad Administration, United States Coast Guard, Urban Mass Transportation Administration, and Research and Special Programs Administration. The interim final rule (49 CFR part 40) followed closely the Department of Health and Human Services (DHHS) regulation entitled "Mandatory Guidelines for Federal Workplace Drug Testing Programs."

The "DHHS Guidelines," as this document is known, were published in the **Federal Register** on April 11, 1988 (53 FR 11970). They were based on a notice of proposed rulemaking (NPRM) published August 14, 1987, by DHHS, and on comments to that NPRM. The DHHS Guidelines include procedures for collecting urine samples for drug testing, procedures for transmitting the samples to testing laboratories, testing procedures, procedures for evaluating test results, quality control measures applicable to the laboratories, recordkeeping and reporting requirements, and standards and procedures for DHHS certification of drug testing laboratories. The intent of the Guidelines is to safeguard the accuracy and integrity of test results and the privacy of individuals who are tested. The interim final rule modified some provisions of the DHHS Guidelines in order to adapt the Guidelines to the circumstances of transportation industries.

DHHS has informed DOT that, beginning with a November 29-December 1, 1989, conference, it is engaging in a consensus process concerning its testing guidelines and laboratory certification procedures. This effort will include consideration of many of the issues raised in this rulemaking. DOT will participate in this process. Should revisions in the DHHS Guidelines result from this process, DOT could initiate rulemaking to make this Part consistent with those changes. This does not mean that we have plans to change these rules but, rather, that they are not static, and that we intend to keep up with the state of the art in testing procedures.

The Department received over 80 comments on the interim final rule itself. In addition, the Department has incorporated into the docket for the interim final rule and reviewed comments on the NPRMs for the six operating administration drug testing rules that pertain to the DHHS Guidelines and testing procedure issues. This final rule and preamble respond to all these comments.

Response to Comments

1. Testing for Additional Drugs

The interim final rule requires employers to test for five drugs: marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP). Generally speaking, if employers wish to test for drugs other than these five, the interim final rule requires them to take a second, separate sample for this purpose. The "DOT sample" may not be used for this or other purposes.

A number of comments objected to this provision, noting that other substances (e.g., barbiturates, benzodiazapines, alcohol) are abused and can cause safety problems. Some comments said that employers were already testing for these additional substances (often stating that they tested for nine or ten drugs currently), and that the rule would either make them scale back existing programs or increase their testing costs. Under the approach that most of these comments appeared to favor, an employer, where its authority to do so was not otherwise constrained (e.g., by state law or union contract), could ask the laboratory to test the "DOT sample" for any additional substances the employer chose.

When the Federal government requires an employer to conduct drug tests, it seems clear from court decisions that the fourth amendment applies to the testing that the employer conducts in response to the Federal requirement. Fourth amendment considerations would arguably apply to any testing resulting from a urine sample collection required by the Federal government, including discretionary employer testing piggybacked onto the DOT-mandated collection. The employers' discretionary testing would also probably be reviewed by the courts as part of the courts' consideration of the overall validity of DOT drug testing rules.

In determining whether a testing requirement passes fourth amendment muster, courts typically have tried to balance governmental interests underlying the testing requirement and the privacy interests of employees. One of the factors examined by the courts in determining the strength of the governmental interest is the safety necessity of testing. Another factor examined is the extent to which testing procedures protect the privacy interest of employees, thereby limiting the intrusion on rights protected by the fourth amendment.

Courts have upheld Federally-mandated drug testing for the five drugs under the DHHS Guidelines (see for instance *Skinner* v. *Railway Labor Executives Association Skinner*, 109 S.Ct. 1402 (1989)). Testing for additional drugs increases the privacy intrusion of testing. Therefore, a change in this respect may make court approval of DOT-required testing more difficult.

DHHS-approved testing protocols and positive thresholds for drugs beyond the five for which testing is now required do not exist. DHHS certification of laboratories does not extend to testing of any of the additional drugs. Consequently, the uniform standards crucial to the accuracy and integrity of the testing process, which courts have relied upon in upholding Federally-required drug testing, are not now in place for the additional drugs. This absence of uniform standards could also make defense of the DOT regulations in court more difficult.

There are also unresolved practical problems that could result from DOT permitting employers to use the "DOT sample" to test for additional drugs. Many of the additional substances commenters expressed a desire to test for are widely available as prescription drugs (e.g., barbiturates). The Medical Review Officer's task in determining whether the drug use indicated by the test is legitimate (and hence not a verified positive) is likely to be significantly more difficult in dealing with legal prescription drugs. The use of DOT-mandated tests to discover the presence of a variety of legal prescription drugs, and therefore to permit employer inferences about otherwise confidential medical conditions, could not easily be prevented.

For these reasons, the Department believes that it is inadvisable, at this time, to grant employers the discretion to test the "DOT sample" for additional drugs. As under the interim final rule, employers wishing to test for substances other than the five drugs for which testing is mandatory must do so using a second, separate sample. This means, in practice, that the employer would have to direct an employee to go to the collection site, do the DOT collection (including providing the sample and completing the paperwork), and then (either at that time or a subsequent time) return to the collection site and provide the "employer sample." In no case, under DOT regulations, would it be proper for the employer to direct the employee to fill one container and then pour off the urine into separate "DOT" and "employer" collections. Nor would it be appropriate for the employer to retain any "surplus" urine in excess of the 60 ml "DOT sample" to be used for the employer's purposes. These approaches would use the DOT-mandated collection to acquire urine to be used to test for additional drugs or for other purposes, and would raise the whole set of concerns that lie behind the Department's decision on the additional drugs issue.

At the same time, the Department is well aware of the costs and administrative burdens implicit in the "second, separate sample" approach. The concerns of employers who wish to test employees for other drugs which may impair safety are legitimate. Consequently, the Department will consider additional rulemaking to deal with all aspects of this problem. Such a rulemaking would be intended to explore means of responding to employers' concerns that would avoid or mitigate the problems we see with permitting employers to test for additional drugs, including the identification of appropriate additional drugs for which testing is warranted and the establishment of appropriate testing protocols for those drugs. The Department will also continue its contacts with DHHS and the Department of Justice in an attempt to determine if a resolution of this problem can be reached that can overcome current practical and legal obstacles.

2. Laboratory Issues

a. *Use of laboratories not certified by DHHS.* Comments suggested that the requirement to use only laboratories certified by DHHS be eliminated. In the alternative, comments suggested that laboratories certified for drug testing by the College of American Pathologists (CAP) or other recognized state or private certifying agencies could also be used, at least in some circumstances (e.g., screening tests, tests at remote sites), if not across the board. Comments cited the cost of the DHHS certification process and a concern about the available capacity of DHHS-certified labs as reasons for this request, as well as asserting that other certification programs (e.g. that operated by CAP) were equivalent to the DHHS system. In addition, comments mentioned satisfactory, existing relationships between labs and employers, which neither wanted to sever. Some comments asked for a transition mechanism to permit labs to complete the DHHS certification process without having to sever existing relationships with transportation employers.

The Department continues to believe that the DHHS certification mechanism is the best guarantee of error-free drug testing available. Its requirements are more stringent, and its inspection and quality control measures more thorough, than any other existing certification mechanism. This not to say that other certification systems, such as that of the CAP, are necessarily inadequate, only that in a program dependent for its success on the unerring accuracy of lab work, the Department is justified in insisting on the highest available standards. These standards have been recognized in court cases upholding Federal drug testing programs. To the extent, in the future, that other certification programs are recognized as equivalent by DHHS, to whose expertise the Department gives substantial deference, the Department can consider at that time permitting laboratories certified under those programs to participate.

At present, DHHS has certified 37 laboratories, which DHHS estimates to have an annual capacity of over 20 million tests. DHHS expects to certify a number of additional laboratories by year's end. This should provide capacity well in excess of that needed for all testing required under DOT rules (which by 1991, is projected to result in 3–6 million tests per year).

We recognize that some laboratories that currently conduct drug testing for transportation companies may choose not to seek DHHS certification, for reasons including costs. Such laboratories could lose some existing business. However, the Department believes that this situation does not warrant eliminating the requirement for DHHS certification, which would have serious adverse consequences for the Department's entire drug testing effort.

b. *On-site testing.* Some employers, particularly in the maritime industry, asked that the rules allow on-site testing. That is, rather than sending the initial screen test to a DHHS-approved lab for analysis, the employer would use a screen test, the result of which could be read at the collections site. If the screen test were negative, the individual would start or continue to work. If it were positive, the individual would be kept from working in a safety-sensitive position until and unless a laboratory or MRO declared the test negative. (Some employers said they would continue to pay an employee in the interim.) The advantages claimed for this approach are that it allows a quick turnaround of results, is helpful in avoiding disruptions in operations, and that it reduces the likelihood of drug users actually performing safety-sensitive functions.

In the Department's view, these claimed advantages are outweighed by the problems involved with on-site testing. With on-site testing, particularly if testing technicians have not been extensively trained, error rates are likely to be considerably higher than for tests conducted in DHHS-approved laboratories. These error rates include substantially more false negatives as well as more false positives, meaning that on-site testing could result in inadvertently allowing drug users to work in safety-sensitive jobs (since negatives would not be sent for confirmation tests). The protection for employees afforded by use of a DHHS-certified lab (indeed, any lab at all) is wholly absent at the screening test level. Nor have the comments' assertions persuaded the Department that unreasonable costs or delays will result from using DHHS-certified laboratories for testing.

With on-site testing, an employee or applicant may be deprived of an

opportunity to work and may be stigmatized as a drug user based on a less accurate type of test with fewer protections. For an employer to promise back pay, or continuing pay, to an employee while a confirmation is pending is well and good, but it is not a complete answer. It does not deal with the very real career impact of even a temporary identification of someone as a drug user and (especially in the quick turnaround situations emphasized by maritime commenters) does not address the lost job opportunities of applicants.

The Department must balance the sometimes competing, legitimate interests of both the employers and the employees its rules affect. By allowing on-site testing, we would shift the balance too far away from the employees' concerns. Like other testing procedure issues, on-site testing is likely to be discussed in the DHHS consensus process.

c. *Other comments.* One comment suggested that DOT or the labs themselves should notify their DOT-regulated clients if DHHS suspends or terminates their certification. We believe that it is not necessary to make this suggestion a regulatory requirement. However, in the event that a laboratory does lose its certification, we believe that the laboratory should notify its clients of the fact. Should laboratories fail to do so, the Department can consider, at a future time, adding a regulatory provision to this effect.

Comments suggested that all employers should be required to conduct laboratory inspections, either directly or through a neutral third party. We believe that adding such a requirement is unnecessary, in light of the extensive DHHS certification process. It would also be unduly burdensome, not only to employers (especially to small employers) but also to laboratories, whose operations could be disrupted by "inspectors" representing hundreds of employers walking through their facilities.

One comment suggested two levels of certification; one for performing screening tests and the other for performing confirmation tests. This comment dovetails with comments suggesting that a local laboratory should be allowed to perform the screening test and then send positive screens to a DHHS-approved lab for certification. On the other hand, another comment suggested that no subcontracting be allowed. In the Department's view, the existing provision (all testing of a particular specimen must be done within a single DHHS-approved lab, but one DHHS-lab can subcontract a portion of an employer's testing contract to another DHHS-certified facility) remains a good middle ground among these positions. The existing rule maintains laboratory quality and accuracy by insisting on full DHHS certification, and avoids chain of custody complications by requiring all work on a specimen to take place within one lab facility. At the same time, it permits some flexibility for employers who may wish a "master contract" with one lab but who find it convenient to have samples processed in various parts of the country.

One comment suggested authorizing union participation in laboratory inspections. The Department believes that union participation in the inspection process is best left to the collective bargaining process. Where labor and management agree to include representatives of both in an inspection, nothing in the regulation would stand in the way.

3. Blind Testing

The interim final rule required blind testing at the levels specified in the DHHS guidelines (a number equivalent to 50 percent of tests submitted in the first 90 days, up to 500; ten percent of samples in each succeeding quarter, up to 250) for all employers who would submit 1000 samples or more a year. Employers who would submit fewer than 1000 samples per year would not have to submit blind samples, if they used a laboratory to which someone else (e.g., a Federal agency, another DOT-regulated employer) submitted blind samples.

A substantial number of comments, citing what they viewed as the trouble and high expense of submitting blind samples, said that employers should never have to submit these samples. It was sufficient, in this view, to rely on the DHHS certification process. Other commenters suggested reducing the number of blind samples submitted, either by using a lower percentage (e.g., between one and five percent) or a small absolute number of specimens (e.g., between two and eight per quarter). Still other comments, to the contrary, suggested that all employers should submit blind samples, lest laboratories treat samples from a particular employer with less care because that employer is known not to submit blind samples.

The Department believes that blind sampling is an important quality control measure. Blind testing does not duplicate DHHS certification measures; it is over and above those measures. In addition to its function as a quality control technique to make sure that labs stay sharp, it tests the entire collection process. Consequently, while the Department is aware of the cost implications of blind testing, we do not believe that it would be a good idea to eliminate the requirement that employers submit blind samples. (It should be noted that blind sample costs appear to be getting lower, with a number of suppliers having informed DHHS that they plan to provide samples for between $10 and $20 each.)

However, after consulting with DHHS, we believe that the quality control objectives of blind testing can be achieved with fewer blind samples. Moreover, we believe that the administration of blind sampling can be simplified by dropping the two-tier (first vs. subsequent quarters) approach of the interim final rule and by expressing the blind sampling rate as three blind samples per 100 employee specimens, rather than as a percentage. This means that, over whatever period of time it takes for an employer to submit 100 employee specimens (whether a week or a number of years), the employer would submit three blind samples.

An employer would not have to submit more than 100 blind samples in any calendar quarter. This is a high maximum; an employer would have to be submitting over 3300 employee specimens in a quarter to reach this level. A DOT agency could raise the maximum in a case when a party (e.g., a very large consortium having several major employers as members) would submit an unusually large number of specimens. This authority would be used only rarely, in all likelihood.

With respect to smaller employers, the Department remains reluctant to impose additional financial burdens. Nevertheless, we believe that there is merit in the contention that the knowledge that even small employers will submit some blind samples is an important quality control measure that will deter potential carelessness on the part of laboratories and help employers discover problems in the processing of samples. Consequently, the Department will require all employers to submit blind samples at the three per 100 specimen rate. In submitting blind samples, smaller employers (those with fewer than 2000 covered employees) could submit all blanks or submit two separately labeled portions of a specimen from the same non-covered employee to make sure that the analyses were the same. These approaches would allow smaller employers to minimize costs. In addition, since employers with fewer than 2000 employees who are scheduled to begin testing in December 1989 or early 1990 will have had short notice of having to do blind testing,

these blind testing requirements will not go into effect for them until 180 days from the date this rule is published. This "grace period" will allow these employers time to make arrangements for blind testing.

When a consortium submits blind samples, it does so collectively on behalf of all its members. The individual members would not need to submit any blind samples independently. The consortium would submit three blind samples for every 100 samples it submitted on the collective behalf of its members.

4. Positive Levels

Several comments requested that the regulation provide more stringent positive levels for one or more drugs. Marijuana was the drug most often mentioned in this connection. There were a number of suggestions for a screen positive level of 20 nanograms per milliliter (ng/ml), with a confirmation level of 10 ng/ml. (The interim final rule called for 100 and 15 ng/ml for screen and confirmation levels, respectively). Other suggestions included lowering the amphetamines screen and confirmation levels from 1000 and 500 ng/ml, respectively, to 500 and 300 ng/ml. One comment suggested a 150 ng/ml screen level for cocaine (the interim final rule established 300 ng/ml for this purpose). The argument, essentially, is that by tightening cutoff levels, especially at the screen test level, more persons using drugs would be caught.

As the comments indicate, there are a variety of preferences on the subject of positive levels. After consulting with DHHS, we believe that the existing positive levels best achieve a reasonable balance between the objectives of treating as positive significant amounts of drug metabolites in an employee's system while treating as negatives smaller quantities of metabolites that could result from such sources as passive inhalation, cross-reactivity, or ingestion of food products. Tightening positive thresholds, especially at the screen test stage, would probably increase program costs, as there would probably be a higher number of initial tests requiring confirmation (and a lower percentage of screen positives that confirmed positive). DHHS is likely to consider this issue in its consensus process on guideline issues, and the Department can revisit the issue following this DHHS consideration.

5. Observed Tests

This issue pertains to the circumstances, if any, under which direct observation of an employee providing a urine sample is permitted or required. Since direct observation makes the collection process more intrusive, the interim final rule limited direct observation to four circumstances in which there is reason to believe that a particular employee may tamper with the specimen.

Some comments requested that this limitation be relaxed or eliminated, allowing greater discretion for observed collections. The Department did not adopt this suggestion, in the view that existing safeguards in part 40 are adequate to prevent tampering and that direct observation, because of its increased intrusiveness, should be strictly limited. Limitations on direct observation are one factor in the balance between privacy and safety necessity considered by the courts.

Other comments opposed all direct observation. The Department did not adopt this comment either, believing that where, for example, there is strong evidence of tampering, direct observation is needed to ensure the integrity of the collection process. Some comments specifically opposed direct observation as part of follow-up (i.e., post-positive) testing, while other commenters favored this practice. The Department believes that direct observation may be a useful tool in follow-up testing. For example, some kinds of drug use (e.g., cocaine addiction) may be very difficult to treat; substance abuse experts suggest that many people undergoing rehabilitation suffer relapses of cocaine use. An individual who has returned to work after rehabilitation but has suffered such a relapse may have a greater incentive to attempt to beat a follow-up test, because the employer may not provide a second opportunity for rehabilitation. If the employer or EAP counselor believes that this may be the case, the opportunity for direct observation should exist.

In this connection, it should be pointed out that, under the regulation, direct observation is mandatory only when the collection site person observes behavior clearly indicating an attempt to tamper or when the specimen temperature is outside the normal temperature range and an oral body temperature reading is refused or is inconsistent with the specimen temperature. In follow-up testing and when the specific gravity and createnine content of a previous sample are below the regulatory standards, the employer has discretion to require direct observation.

Other comments suggested that the MRO should determine when a collection should be directly observed. While, in some situations, the MRO may be involved in this determination (and a company may use an MRO for this purpose), the Department does not think it would be a good idea to mandate this involvement. For example, MROs often may not be located near the testing site, making their mandatory involvement impractical.

Some comments opposed, and others favored, the current requirement that a higher-level supervisor of the collection site person, or a designated employer representative, concur with a decision of the collection site person to require direct observation. The Department believes that this requirement of the current rule is sound, as a check on the decision of a staff person to require an intrusion on privacy, and should be retained.

One comment suggested that a directly observed collection could be made if either creatinine levels or specific gravity on previous test (rather than both, as under the current rule) were below the regulatory standard. In the Department's view, it is preferable to retain the current provision. Given the additional privacy intrusion involved in a directly observed collection, it is preferable to have two, rather than one, indicators of possible dilution of a sample before proceeding to an observed collection.

6. Testing Procedure Issues

a. *Collection site person issues.* Some commenters requested that the Department establish training procedures or standards, or establish testing requirements, for collection site personnel. The Department does not believe such requirements are necessary. The interim final rule provides that, if not a licensed medical professional or technician, a collection site person must be trained for his or her function. This training is intended to be training to proficiency (i.e., the person must be trained sufficiently to ensure that he or she will perform the functions of the job competently). We would also point out the existing requirement for the provision of instructions to collection site personnel.

The Department does not believe that it would be productive to require all collection site persons to conform to a single training curriculum developed by the Department. If there is sufficient interest (expressed, for example, at forthcoming DOT drug conferences or in correspondence to the Department), the Department could consider cooperating in the development of a model training module. More extensive requirements,

such as testing or certification, are likely to be unduly costly. Such requirements could also interfere with reasonable cause or post-accident tests, which sometimes must be conducted at medical facilities that are not regular collection sites.

One comment suggested that supervisors of employees should not be permitted to collect specimens from the employees. The concern of the commenter appeared to be that a supervisor might have the appearance of a conflict of interest in collecting a specimen from an employee the supervisor did not like. The Department agrees that it would be preferable, as a general matter, for supervisors not to collect specimens from their own subordinates. Consequently, we have altered the rule to provide that the direct supervisor of a covered employee may not act as the collection site person for that employee, except where this is impracticable (e.g., on a ship at sea, where the only person or persons available and qualified to do collections have a supervisory relationship with the employees). If individual DOT agency rules impose more stringent provisions, the more stringent requirements apply.

One comment asked that the employer's own personnel be permitted to conduct collections. The current rule permits this practice. With the exception stated above concerning direct supervisors, the Department will permit this practice to continue. It was also suggested that collection site personnel can be licensed by any state or jurisdiction. Again, this is already the case (and for MROs as well as medical professionals or technicians who collect specimens).

A number of comments suggested that the collection site person should be able to be of the opposite gender from the employee, when a same-sex person is not available. Under the current rule, a collection site person must be of the same gender as the employee in only two circumstances. One is that the individual who watches an employee provide a directly observed sample must be of the same gender as the employee. It should be pointed out that only the observer (who does not need special training) must be of the same gender as the employee. An opposite gender collection site person could still perform other collection functions, as long as a same-gender observer were used.

The second case involves and individual who "monitors" a collection. Such an individual, if he or she is not a medical professional or technician, must be of the same gender as the donor. A collection site person "monitors" a collection, for this purpose, only if he or she is in close proximity to the employee as the employee provides the sample, such that the collection site person can hear the employee's actions. For example, if the collection takes place in a public rest room, in which the employee goes into a partially partitioned stall to provide the sample, while the collection site person remains in the common area of the rest room, the collection site person would be "monitoring" the collection. On the other hand, if the collection takes place in a facility (like many medical facilities) in which the employee goes into a separate room, with a fully closable door, to donate the sample, while the collection site person remains outside, "monitoring" would not take place. In the former case, the person monitoring the collection would have to be either a medical professional or technician (of either gender) or someone without medical training who is of the same gender as the employee.

The Department believes that these requirements are important to safeguard employees' privacy. While we understand that there may be occasional situations in which the requirements make it difficult or more costly to conduct collections, we believe that, on balance, the privacy interests of employees justify these costs.

Another comment suggested that the collection site person should not be permitted to leave the collection site before the specimen is sealed and labeled. This requirement is already part of the regulation and will be retained. It was also suggested that, to increase efficiency, a collection site person could work with more than one donor at a time, with appropriate safeguards. The current rule limits the collection site person to working on one specimen at a time "in order to promote security of the specimens, avoid distraction of the collection site person and ensure against any confusion in the identity of specimens" (49 CFR 40.25(d)). These reasons remain valid, and the Department is retaining this requirement. This provision does not preclude more than one collection site person from working in a particular collection site, however, as long as each person supervises only one donor at a time.

b. *Sample Quantity.* Comments mentioned the "shy bladder" problem, in which an individual, for physiological or psychological reasons, is unable to produce sufficient urine for a sample. The Department does not believe it would be consistent with the intent of the testing program to excuse from testing persons solely on the basis that they claimed to have this problem or who, on a first attempt, were unable to produce a specimen. In its internal program, the Department, consistent with the DHHS Guidelines, tells the individual to drink additional fluid and wait a reasonable time before trying again to produce a sample. During this time, the individual remains at the collection site or otherwise under supervision. If, after a reasonable time, the individual cannot provide the sample, the individual is scheduled for a subsequent unannounced test. If the result is the same, the individual would be directed to see a physician, whose evaluation of whether there was a genuine problem or a refusal to take a test would be provided to the employer. The rule adopts a similar system, with refinements taking into account the differences among different types of testing.

Some comments also suggested, as a general matter, that a sample smaller than 60 ml (e.g., 30 ml) would be adequate. The purpose of a 60 ml sample is to allow sufficient urine for multiple GCMS confirmation tests (if the screen test is positive for multiple drugs) and for a retest, if one is requested. While a smaller quantity may be sufficient in many cases, the 60 ml sample size leaves a greater margin of safety for situations in which multiple aliquots are needed. (We would suggest, however, that if a sample reaching the laboratory inadvertently is a small amount short of the 60 ml, the test need not necessarily be cancelled. The test should be cancelled only if the amount of urine proved insufficient for all necessary analysis (including a reserve of 10 ml for possible retesting).)

A comment also suggested that female employees be excused from testing during their menstrual periods. The Department does not believe that this is essential, either for the integrity of the testing process or the comfort of employees. We recommend that when an employee states to the collection site person that the two events coincide, the collection site person should note the fact on the chain of custody form. If any substances (e.g., blood) or other chemical changes in the urine made a valid test impossible, the laboratory would cancel the test.

c. *Additional protections for employees*—Some comments urged a requirement for "split samples." That is, the employee would provide a sample which would be divided into two containers. The two containers would be separately labeled. One would be sent to the laboratory for analysis while the other would be stored (either at the same lab, a second lab, or an employer

storage site). If the first sample were positive, the second sample would be tested. If the second result were negative, the test would be cancelled. The comment suggested that this system would provide an extra measure of protection for employees against employer or laboratory error.

The Department does not believe that split samples should be required as part of this regulation. Given the stringent safeguards embodied in these procedures (e.g., concerning collection, chain of custody, DHHS-approved labs, GCMS confirmation tests, and MRO verification), the likelihood of a false positive is extremely low. (For example, the Department, in over 30,000 tests run under the DHHS Guidelines, has never had a false positive.) The extra costs and administrative burden of a split sample system would be unlikely to provide significant additional, necessary protection for employees. If employers wish to use a "split sample" approach, however, the rule permits them to do so. It should be emphasized that doing so is completely voluntary; at the same time, the Department sees no compelling reason to prohibit the practice.

The Department is adopting another suggestion to increase employee confidence in the process. This comment is to require the employee to be provided with a prepackaged specimen bottle (and collection container, if applicable) prior to providing the sample. We recommend, in addition, that the collection site person shall allow the employee to select the specimen bottle and collection container he or she will use.

The Department has not adopted a suggestion for having DOT-established quality assurance guidelines. This matter is adequately handled by the DHHS certification process and blind testing requirements. A related suggestion, to allow employees who test positive access to all laboratory records, is adequately handled by the existing rule (see § 40.37).

Among other suggestions the Department is not adopting are to have an employee representative required to be present with the tested employee at the collection site (which potentially would cause crowding, delay, and interference with the process), to give employees an hour after coming off the job before taking a random test (which would cause unnecessary delay and expense), to prohibit tests during rest periods (which would needlessly complicate the timing of the testing process and make it more expensive), and to establish a separate positive threshold for retests of positive specimens (a retest is simply for the presence of the drug, making this step unnecessary). The Department agrees with comments suggesting that needed medical treatment should not be delayed in order to collect a specimen and the rule so provides.

d. *Other issues*—A comment suggested requiring a permanent collection site logbook. The DHHS Guidelines contain this requirement; the DOT procedures deleted the requirement as an unnecessary administrative burden in light of the chain of custody form called for in the rule. The Department continues to believe that the rule's chain of custody form system is adequate (one of the copies of the form is retained by the collector) for records purposes and that a permanent log book would be duplicative.

Another suggestion was to make the collection procedures of section 40.25 voluntary instead of mandatory. The Department did not adopt this comment, because doing so could result in inconsistent and potentially inadequate protections for the integrity and accuracy of the collection process.

It was suggested, with reference to § 40.25(f)(16), that it was unnecessary to send to the lab both a suspect sample and a retest sample. Since it is possible that the initial specimen could be valid, we believe that it makes sense to send both.

A comment objected to ever using public bathrooms, contending that their security could not be assured. When a public bathroom is used, it must be posted against access by persons not involved in the drug testing process and access must be controlled by the collection site person. These existing safeguards are sufficient, in the Department's view.

It was also suggested that collection site persons show an ID to the employee upon request and provide a receipt for personal belongings surrendered by the employee. We believe it is fair that, since the employee must show ID to the collection site person, the collection site person would reciprocate if asked. If surrendered personal belongings do not remain in the same room with the collection site person and the employee, we also believe it is reasonable for a receipt to be provided. The rule has been amended to provide for both these safeguards.

It was suggested that an employee not have to wash his or her hands prior to giving the sample. Because it is possible to conceal adulterants under a fingernail, we believe this practice should continue. We agree with a comment that it is preferable to store specimens in a secured area (e.g., a locked refrigerator) prior to shipment, and we recommend this practice, but we do not think it necessary to require this practice in the rule. The rule's safeguards for specimen security are sufficient, in our view, and not every location where samples are taken may have something like a locked refrigerator (e.g., remote work sites). Nor do we believe it is necessary to record the specimen temperature in every case; recording normal temperature results would simply be additional paperwork not adding to the integrity of the process.

7. Medical Review Officer Issues

a. *Who performs MRO functions?*—A number of comments said, in effect, that no one should have to perform MRO functions, since the concept of an MRO was an impediment to the efficient functioning of a drug testing program and that the MRO should be deleted from the rule. The Department continues to believe that having an MRO is crucial to a good drug testing program. The Department's program is intended to deter and detect the prohibited use of certain types of drugs, in the interest of transportation safety. Many substances (e.g., opiates, cocaine) have legitimate medical uses as well as prohibited uses. Laboratory machines, however accurate, cannot make this distinction; they just measure quantities of a chemical in urine. A trained, medically knowledgeable person—the MRO—is essential to be able to distinguish licit from prohibited use of substances. In the absence of such informed medical judgment, we believe that the system would be less likely to achieve its objective and would be very unfair. Like a sound chain of custody, GCMS-confirmed tests, and DHHS-certified labs, having an MRO is a safeguard that the DOT program cannot do without.

Some comments suggested that a staff member of a testing laboratory should be able to function as the MRO. Since laboratories may have qualified physicians on their staffs, this could be both a convenience for the many employers who do not have staff physicians of their own and a useful marketing tool for laboratories. However, the Department is concerned that there could be a conflict of interest, or the appearance of such a conflict, between a doctor's role as a staff member of a laboratory and the MRO's responsibility to determine whether test results are scientifically sufficient. To deal with this problem, the Department is amending the regulation to provide that if a laboratory wants to provide MRO services, it must establish a

separation of functions to guard against the possibility of a conflict of interest. For example, the laboratory could spin off an organizationally separate subsidiary to perform MRO functions or could erect what is sometimes called a "bubble" or "Chinese wall" around the MRO, to ensure that the MRO is not subject to communications or influences that could create the appearance or reality of a conflict of interest. In no case could the physicians performing as MROs have responsibility for, or be subject to the supervision of those who have responsibility for, the drug testing or quality control operations of the laboratory.

Comments also suggested that MROs should be able to have non-physicians on their staffs who would take care of administrative duties, making contacts with employees, etc. The current rule does not prohibit this practice, and an amendment is not needed for this purpose. MROs are likely to need staff persons for administrative duties, and these staff may certainly make the initial contacts with employees (e.g., place calls to those who have tested positive to inform them that the MRO needs to talk to them). An appropriately medically trained staff person (e.g., a nurse with substance abuse training) may gather information from an employee about the employee's explanation for a positive result. In every case, however, the MRO must make the decision about whether, and talk to the employee before, a confirmed laboratory positive is verified positive. No staff person can make this decision for the MRO. All persons working for the MRO are bound by the same requirements for confidentiality to which the MRO is subject.

Comments disagreed on whether non-physicians could serve as MROs. The Department believes that it is important for the MRO to be a physician, in order that a person with substantial medical training be in a position to make the critical medical judgment about whether an individual's drug use is legitimate.

b. *Which tests does the MRO review?*—Some commenters thought MROs should not have to review negative tests. The current regulation, while requiring negatives to be sent from the lab to the MRO, does not require substantive review of negatives by the MRO. The MRO's function with respect to negatives need be only an administrative one, and ought not add significant costs to the process, since only administrative processing fees (as distinct from fees for professional medical services) would seem to be involved. The rule now explicitly states this point.

This administrative role is an important one, however. If negatives were sent directly to the employer from the laboratory, while positives were sent to the MRO, the employer would know for certain that some identifiable employees were "lab negatives" and others were "lab positives" whose tests the MRO did not verify positive. The employer would know this simply from the fact of whether it got a negative result from the lab or the MRO. A "lab positive/verification negative" employee could easily be stigmatized as a drug user, or be subject to employer inquiries about medical use of drugs. This would be contrary to the intent of the rule with respect to employee confidentiality.

It was also suggested that MROs should not have to review positive pre-employment tests, or not review any tests except post-accident tests, or not review any tests at all. Laboratory positive tests not going to the MRO would go directly to the employer, who could take action against the employee or applicant immediately upon receipt. MRO review would occur only if an employee appealed the positive test. The advantage of this approach, comments said, is that it would allow employers to act quickly to remove drug abusers from safety sensitive positions, rather than incurring potential liability for an accident that might happen during the course of MRO verification.

The Department has not adopted this comment. The Department's rules are intended to result in the removal from safety sensitive positions only those individuals who are determined to have engaged in prohibited drug use. Until an MRO verifies that a positive laboratory result represents prohibited drug use (e.g., that there is not a legitimate explanation for the laboratory result), the condition on which employer action under the regulations is premised has not come into being. MRO verification prior to employer action is essential to the accomplishment of the purpose of these regulations.

The Department does not see any policy distinction between the need for MRO verification of one sort of test and another. In any case, a confirmed positive test resulting from legitimate use of a drug, if not subject to MRO verification procedures, can result in economic harm to, and stigmatization as an illicit drug user of, an innocent party. The final rule will continue to require MRO verification for all tests.

Comments asked that MROs, in making verification decisions, be able to consider results of tests of the employee's urine made in other labs. This issue is addressed by § 40.33(b), which provides that MROs may not consider results of urine samples that are not obtained or processed in accordance with the DOT procedures. For example, if a "split sample" is taken, all procedures affecting the second part of the sample must be the same as for the first, and all tests must be done in a DHHS-certified laboratory. Only under these conditions could the MRO consider a result from a second lab. The MRO could not consider samples taken under other conditions or at a different time. If the two lab results turned out to be different (e.g., one positive, one negative), the MRO would cancel the test and contact the laboratory director(s) and attempt to discover the reason for the discrepancy. (The same procedure would be followed if a retest of a "positive" specimen had a negative result.) As following any cancelled test, the employer would direct the employee to take another subsequent test, if appropriate.

c. *MRO procedures*—Some comments expressed concern that the regulation requires MROs to talk to employees face-to-face, a clear impracticality in many instances. The MRO must provide an opportunity for an interview of an employee testing positive as part of the verification process, but this conversation can happen via telephone or other means as well as a face-to-face discussion. If the employee, however, affirmatively turns down the opportunity (e.g., tells the MRO he does not want to discuss the matter), the MRO may proceed with verification.

The timing of the verification process concerned a number of commenters. For example, suppose an MRO is unable to locate an employee, or the employee does not return the MRO's calls. How long is the MRO supposed to wait before verifying a test as positive? The Department has incorporated the following procedure into the regulations. The MRO makes an active attempt to contact the employee. This is intended to be the primary means by which the employee is contacted; other means are mechanisms intended to be used only if the MRO's direct attempt is unsuccessful. If this attempt does not succeed after the MRO has made all reasonable efforts (i.e., the MRO has tried all the means of getting hold of the individual within a reasonable time that can reasonably be expected to be productive) the MRO would contact a designated employer representative. (What constitutes a reasonable time, and what reasonable efforts must be

made, are matters for the MRO's judgment, which can vary with the circumstances of different industries or employers. For example, the time, and the sort of efforts that would be involved, may differ depending on whether the employee involved is a truck driver who is on a cross-country trip, as opposed to a mass transit bus driver who checks into a terminal every morning before starting to drive.) The MRO will not inform the employer representative of the reason for this request, and the employer representative must take appropriate steps to safeguard confidentiality.

The employer representative must contact the employee and tell the employee to contact the MRO as soon as possible. This should be done, whenever possible, prior to the employee's next performing his or her safety-sensitive function.

If the employer representative is unable to contact the employee, the employer could place the employee on medical leave or temporary medically unqualified status. The test would still not be a verified positive until the employee had the opportunity to talk with the MRO, but the individual would not be performing a safety-sensitive function in the meantime.

In order to prevent undue delays covered by an employee's refusal to contact the MRO, the MRO could verify a confirmed positive test result if, five days after a documented contact between the MRO or designated employer representative that informed the employee that he or she was to talk to the MRO, the employee had failed to do so. The rationale for the provision would be that, having been told to talk to the MRO, the employee, by declining to do so, has waived the opportunity to prevent information concerning possible legitimate explanations for a confirmed positive drug test. As a safeguard for employees, the MRO could review the verification if the employee demonstrated that circumstances prevented the contact (e.g., the employee produced medical records to show that, the day after the employer contact, the employee was seriously injured in an automobile accident and was hospitalized for several days). If the MRO "reopened" the verification in such a case, and the employee was able to demonstrate a legitimate medical explanation for the confirmed laboratory positive, the test result would be changed to a negative.

Another suggestion was that the laboratory should routinely provide the quantitation of positive tests to the MRO, rather than only upon MRO request. The Department does not see the need for such a requirement. The MRO typically needs to know only that a test was confirmed positive. In most cases, the quantitation is not relevant to the MRO's job. When the MRO, for some reason, believes that quantitation is needed, the laboratory is obligated to provide it. This seems sufficient for accomplishing the purposes of the rule.

A question has been raised concerning whether the MRO may begin verification immediately upon receiving notification from laboratory of a confirmed positive result (e.g., by fax or computer link). The MRO may indeed begin the verification process at this point, by contacting the employee and obtaining the employee's explanation of the positive result. However, the MRO is not to declare a verified positive until he or she receives the hard copy of the original chain of custody form from the laboratory. This is because, prior to determining that the test is a verified positive, the MRO verifies the identifying information and the facial completeness of the chain of custody (i.e., determines that, on the face of the document, all the sign-offs are in the right places).

There was a request for clarification concerning whether one MRO could serve all the employers participating in a consortium. This is the case; indeed, the main purpose of a consortium is to allow employers to share the services and costs of MROs, collectors, laboratories, etc.

d. *Confidentiality issues.* Under the current regulations, the MRO is directed to tell the employer only whether the drug test is positive or negative (see § 40.27(g)(3)). This implies, but does not explicitly state, that the MRO would not inform management of other information developed in the verification process that could affect safety. Some comments pointed out that it puts an employee in a difficult position if, in order to explain a confirmed positive result as legitimate drug use, he or she must reveal information which will be passed on to an employer who then may take adverse action against the employee as a result. The passing on of this information may also raise issues about whether the MRO has breached a duty of confidentiality.

On the other hand, if the MRO learns about legal use of medications by an employee that may cause or reveal a safety problem, the MRO may have legitimate concerns about his responsibility to protect public safety and his liability in any subsequent accident attributable to the employee's use of the legal drug.

To balance these considerations, the Department has incorporated the following approach in the final rule. The MRO would inform the employee, before beginning the verification interview, that the MRO could transmit to appropriate parties (e.g., the employer, a certifying physician, a DOT agency) information concerning medications being used by the employee or the employee's medical condition only if, in the MRO's medical judgment, the information indicated that the employee may be medically unqualified under applicable DOT agency rules or would otherwise present a safety hazard. Information could also be transmitted to third parties if DOT agency regulations so provide (e.g., a DOT agency regulation calling for the provision of information to the National Transportation Safety Board in an accident investigation). The MRO could then transmit the information (e.g., that the employee was regularly taking medication that made him very drowsy while on the job).

Another confidentiality issue concerns formal proceedings (e.g., lawsuits, grievances, arbitrations) in which an employee challenges action taken by an employer as the result of a drug test. Normally, information about drug tests (see §§ 40.27(g)(3), 40.35, and 40.37) is releasable only with the consent of the employee. However, it would be unfair if, in an adversarial proceeding, one side had access to information which the other did not. Consequently, we have clarified the regulation to provide for the release of relevant information to management in the context of such a proceeding.

8. The Chain of Custody Form

The Department received a substantial number of comments concerning the chain of custody form. The Department, working with DHHS, has drafted a revised chain of custody form, which it tested in the Department's internal program. In addition, a number of comments included suggestions for revising the form. The Department has produced, from these sources, a revised chain of custody form for use by employers covered by DOT drug testing regulations. It is set out at appendix A. The portions of this regulation pertaining to the form (see § 40.23(a)) have been changed from the interim final rule to be consistent with the new form.

Employers are not required to "photocopy" this form; they may gather the information in a somewhat different format. However, employers are required to gather the information called for in § 40.23(a) and may not gather information inconsistent with that called for in these rules (e.g., information that

could compromise employee confidentiality). A form that, for example, was only a three-part form rather than a six-part form, or which failed to include the certifications, chain-of-custody provisions etc. called for in the regulation would not be consistent with part 40 requirements.

It should be noted that the back of copy 4 of the form (the employee's copy) contains space on which the employee can note, as his or her own private "memory jogger," medications or other substances which he or she is taking. This use of the space by the employee is entirely voluntary; employers may not insist on its use, and the information is not intended to be provided to the employer.

The Department is aware that, as testing begins for many employers in December 1989, they may not have time to get copies of the new form printed before testing begins. As a transitional measure, employers may continue to use forms complying with the interim final rule for a reasonable time. All new printings of forms must conform to the revised form. We urge transition to the new form as soon as possible.

9. Recordkeeping and Reporting

One issue mentioned in a number of comments concerns "batch reporting." Section 40.29(g)(1) of the interim final rule requires that the laboratory report all positive and negative results of samples submitted at the same time to the MRO at the same time. Some comments objected to this requirement on the grounds that it unnecessarily kept information from employers about negative tests during the time it took for MROs to verify the positive tests in the "batch." The purpose of the batch testing requirement was to prevent the employer from inferring which employees had positive test results from the lab (even if the tests ultimately were not verified as positives), since this inference could lead to stigmatization of the employees.

The Department believes that the batch reporting requirement is no longer necessary and has removed it from the rule. It is our understanding that, given the individual chain of custody form that would be used predominantly for DOT-mandated drug testing and the way that samples are processed in DHHS-certified laboratories, it is no longer relevant to conceive samples as arriving at and departing from laboratories in easily identifiable batches. Under these circumstances, the Department will permit laboratories to report individual results to the MRO as they become available. Likewise, MROs could report the results to the employer as they become available or, in the case of positives, as they are verified.

The Department will maintain the prohibition on the provision of results from the lab to the MRO by telephone. The potential for garbling of information in voice communications is too great. Provision of results in a written form (e.g., fax, computer link, hard copy) are needed. The Department also recommends that MROs pass on results to employers in a written form, lest mishearing of information in a phone conversation result in mistaken action with respect to an employee.

There were a number of comments concerning the monthly report provided by the laboratory to the employer (§ 40.29(g)(6)). One was that the report should not distinguish between confirmed and unconfirmed positives. The Department has not adopted this comment, on the ground that this aggregate information may be of use to employers and is likely to involve minimal cost. Another comment suggested providing this report directly to unions as well as to the employer. The Department will not mandate transmission of the report to unions, though this may be an appropriate subject for collective bargaining. Finally, a commenter expressed concern that for small employers, the facially aggregated data could provide individually identifiable information about employees. For example, if an employer only had two tests during a month, and one was positive, it would be easy for the employer to infer from the data that a specific other employee had a screen positive. To get around this problem, the rule has been changed to require labs to refrain from sending the monthly report where the data is not sufficiently aggregated to prevent compromise of information about particular individuals. In such a case, the laboratory would not provide the report until a time (e.g., a month or two later) when the data was sufficiently aggregated. (On a similar matter, laboratories and other parties should refrain from billing practices that would permit employers readily to identify individual employee's results.)

Comments suggested that employees should be notified if there is evidence of tampering or other problems with a sample (employees would be notified of a cancelled test, which would be the typical result of such problems) or, with respect to employees who had tested positive recently, if a blind sample resulted in a false positive (unnecessary, in the Department's view, in light of the provisions for retests in § 40.31(D)(6) and the fact that a false positive on a blind sample can result in action against the lab, up to and including the loss of certification). Either of these kinds of actions could also result in investigation by the concerned DOT agency or office. There was also a request for direct notification of employees, not just the MRO, of test results within five days. Since the role of the MRO in determining test results and maintaining confidentiality is very important, the Department believes the existing provision should be retained.

There were various suggestions for changing record retention requirements (e.g., reducing record retention periods, avoiding storing positive samples for a year for possible retests). The Department has concluded that existing record retention requirements are needed to facilitate monitoring of the testing process and keep sufficient safeguards of the accuracy of the process in place. It should be noted that records may be kept electronically or by other means (e.g., microfiche) as well as in paper hard copy.

10. Rulemaking Procedure and Other Issues

Some comments asked that a "waiver" provision be included in the regulation. Such a provision would allow individual employers or industries, on their own or with the consent of the relevant DOT operating administration, to establish different testing procedures from those set forth in the regulation. This would permit the various employers or industries to have testing procedures that fit their circumstances better than the general provisions of the rule, it was said.

The Department has not adopted this comment. The matters about which waivers would most likely be sought, based on the comments, are those on which comments indicated that employers preferred to proceed differently from part 40 (e.g., which drugs are tested for, positive thresholds, use of DHHS-certified labs, use of on-site screening tests, MRO verification of positives). These are matters that the Department has considered and decided in this rulemaking. Having made decisions on these issues, which affect employees as well as employers, the Department does not think it advisable to invite requests by employers to design their own procedures, which could be inconsistent with, and contrary to the rationale of, the provisions of this rule. The result could be substantial inconsistency among employers and industries and the erosion of necessary legal and practical protections for employees, which are crucial to the success of the program.

It should be pointed out that, as an Office of the Secretary of Transportation rule, part 40 is subject to the exemption procedures of 49 CFR 5.11–5.13. Under these procedures, any party may petition the Secretary for an exemption to a rule. The grounds on which an exemption may be granted are narrow. An exemption is granted only on the basis of a showing of special circumstances, not contemplated in the rulemaking, that make compliance with the generally applicable rule infeasible. By special circumstances, we mean circumstances peculiar to the applicant, which are not generally applicable to a class of parties. An exemption request is not a forum for reasserting arguments or positions considered during the rulemaking, or for seeking a *de facto* amendment to the rule. Nor are exemptions granted on the basis that the applicant would find it preferable to proceed in a way other than that set forth in the rule.

On the basis that urine testing is such a bad idea that no set of procedures could redeem it, some comments urged abolishing the procedures (and, implicitly, the entire DOT drug testing program as well). The Department is well aware of the controversial nature of drug testing. The Department is committed to drug testing as being necessary for transportation safety. These procedures are the best means of which the Department is aware to ensure that testing is fair and accurate. Other commenters urged abolishing the procedures or making them voluntary so that employers could devise their own procedures.

Given the number of employers covered by DOT drug testing rules, and the varying resources available to them, the Department believes that consistent procedures that protect the accuracy and integrity of testing and successfully balance the legitimate interests of employers and employees would be difficult to achieve under such a "voluntary" approach.

Some comments questioned the validity of issuing an interim final rule, saying that an NPRM should have been issued first or that a supplemental notice of proposed rulemaking (SNPRM) should be issued before a revised final rule. The Department does not believe that either is called for. Before the issuance of the interim final rule in November 1988, commenters had the chance to address the applicability of the DHHS Guidelines to the DOT drug testing program in the context of six operating administration NPRMs. That the Department decided, as a matter of administrative convenience, to issue one procedural rule applicable to all six operating administration rules rather than incorporating or referencing the DHHS Guidelines or a modification of them in six individual rules does not affect the validity of the rulemaking process. (It should also be pointed out that the DHHS Guidelines themselves were published after an opportunity for public comment.)

After reviewing the comments pertaining to testing procedures made in response to the six operating administration NPRMs and the comments on the interim final rule, the Department is convinced that the issues have been thoroughly raised and responded to, and that a further opportunity to comment in an SNPRM would only delay necessary revisions of the interim final rule, rather than obtain additional useful suggestions. Therefore, the Department is proceeding to a final rule at this time.

A few comments also questioned the underlying legal authority for the rule. The rule is an Office of the Secretary rule, published under the general rulemaking authority available to the Secretary of Transportation. The operating administration rules, issued under the safety and/or grant program rulemaking authority of the several administrations, are the source of the requirement that regulated employers use the part 40 procedures.

Other comments concerned the regulatory evaluation, regulatory flexibility statement, and federalism statement. The costs of drug testing, and of testing according to these procedures, are imposed on regulated parties not by part 40 but by the six operating administration rules. The costs were taken into account in the regulatory evaluations for those rules and do not need to be repeated in connection with part 40.

The same can be said, as a general matter, for the impact of part 40 on small entities. One point made in this connection was that the requirement of part 40 for DHHS certification of laboratories could reduce opportunities for small laboratories. The Department does not believe that this is the case. DHHS certification is available to any laboratory meeting DHHS requirements, which do not include a size minimum. The 37 laboratories certified to date by DHHS include smaller as well as larger laboratories. While some laboratories, including small laboratories, may conclude that the business they would gain through DHHS certification is not sufficient to make DHHS certification worthwhile to pursue, the Department does not believe that this makes a case for altering the standards for participation in the DOT drug testing program, which must remain high in order to protect the integrity of the program.

With respect to federalism, a comment suggested that there may be a federalism impact on state and local laboratory certification standards. The requirements for the use of DHHS-certified laboratories does not in any way affect or preempt state or local laboratory certification standards, which will continue to apply without change within their ambit. Part 40 simply says that for purposes of a new Federal testing requirement, DHHS certification is required in addition to whatever standards laboratories must meet under state or local law.

Section-by-Section Analysis of Changes in the Final Rule

The Department is printing the complete text of part 40, as amended, in order to facilitate its use by affected parties. As a guide to the changes made in this amendment, this section of the preamble lists the changes which this amendment makes to each section of part 40.

Heading. The Table of Contents is changed by deleting the reference to subpart C and by changing the number of the section on the use of DHHS-certified laboratories from 40.41 to 40.39. The reference to the DHHS certification standards has been deleted (as has the old appendix A itself); appendix A now contains the drug testing custody and control form. A reference to 49 U.S.C. 322 has been added to the authority citation. This citation, which is to the statute containing the Secretary's general rulemaking authority, was inadvertently omitted from the publication of the interim final rule.

Section 40.3 Definitions. A definition of "blind sample" has been added. An addition has been made to the definition of "collection site person," providing that unless it is impracticable for any other individual to perform this function, a direct supervisor of an employee shall not serve as the collection site person for a test of the employee. This definition also clarifies what "monitoring" of a drug test means. Definitions have also been added to distinguish three kinds of containers used in the collection process; the collection container, specimen bottle, and shipping container.

Section 40.23 Preparation for Testing. Paragraph 40.23(a), concerning the drug testing custody and control form, has been changed in accordance with the revised form. Paragraph 40.23(b) now

contains, as subparagraph (1), a requirement for the use of a sealed specimen container, which will be presented to the employee for unsealing at the beginning of the test procedure. The existing language of paragraph (b) has been renumbered as subparagraph (2).

Section 40.23 Specimen Collection Procedures. Subparagraph 40.25(e)(2)(i) has been amended by deleting the words at the end concerning the oral temperature not equalling or exceeding that of the specimen. The temperature range provision has been clarified.

Subparagraph (f)(2) contains new language at the end providing that on employee request, the collection site person shall show his or her identification to the employee. Language has been added at the end of subparagraph (f)(4) directing that if an employee requests it, the collection site person shall provide the employee a receipt for any personal belongings. Subparagraph (f)(8) now contains language requiring that the collection site person provide to the individual a sealed specimen container for purposes of giving the sample.

Subparagraph (f)(10)(i) concerns the "shy bladder" problem. The new language provides that if the individual is unable to provide 60 ml of urine, the collection site person shall direct the individual to drink fluids and, after a reasonable time, try again to provide a complete sample. In the case of a post-accident or reasonable cause test, the individual is not required to continue the procedure beyond eight hours from the start of the collection procedure. For other types of testing, another option is provided, under which the employer is notified, and the individual is scheduled for an unannounced drug test in the near future (if an employee) or scheduled for a new preemployment test (if an applicant; of course, the employer need not hire an applicant and the referral for further evaluation or testing is not mandatory in the preemployment situation, if the employer does not want to hire the person). If the individual cannot produce a complete sample within the eight-hour period or at the subsequent test, the employer must refer the individual to a physician for a medical evaluation of whether the problem is genuine or amounts to a refusal to take a drug test. Also in subparagraph (f)(10), new subparagraph (ii) has been added, permitting, but not requiring, the use of "split samples." It should be noted that the test of the second part of a "split sample" is only for presence of the drug(s) found positive on the first test (i.e., the cutoff values of § 40.29 do not apply). A new subparagraph (iii) specifies that, except for split samples under subparagraph (ii), no portion of the sample collected under this part may be used for any purpose other than drug testing required under DOT regulations.

A new paragraph (j) has been added, concerning employees requiring medical attention. The paragraph provides that if the collection is being made from an employee in need of medical attention (e.g., in a post-accident test), necessary medical attention shall not be delayed in order to take the sample.

Section 40.29 Laboratory Analysis Procedures. Subparagraph 40.29(g)(1) has been amended by deleting the last sentence, which required "batch reporting." Subparagraph 40.29(g)(3) has been amended by adding a proviso that the MRO may reveal the quantitation of a positive test result to the employer, the employee, or the decisionmaker in a lawsuit, grievance or other proceeding initiated by or on behalf of the employee and arising from a verified positive drug test (including a challenge by an employee to an action by a DOT agency concerning the employee's medical certificate, license, or other document).

Subparagraph (g)(6) has been amended by adding language providing that monthly reports shall not include data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary in order to prevent disclosure of such data, the laboratory shall not send a report until data are sufficiently aggregated to make such an inference unlikely. In any month in which a report is withheld for this reason, the laboratory would so inform the employer in writing.

Section 40.31 Quality Assurance and Quality Control. In subparagraph (d)(2) of this section, the blind testing requirements have been simplified and the rates reduced. All employers, regardless of size, are covered. Each employer must submit three blind samples for every 100 employee specimens submitted, to a maximum of 100 blind samples per quarter. A DOT agency could increase this maximum if necessary, for extremely large employees or consortiums. For employees with fewer than 2000 covered employees, lower cost methods of supplying blind samples are authorized by subparagraph (d)(4). Blind testing need not begin until 180 days after publication of the rule for employers with fewer than 2000 employees. Subparagraph (5) clarifies that a consortium submits blind samples on behalf of its members.

Section 40.33 Reporting and Review of Results. In paragraph (a), the word "results" at the end of the first sentence has been changed to the words "confirmed positive results from the laboratory" as a clarification, to emphasize that a review of negative results is not necessary. At the end of this paragraph, a sentence has been added to make explicit that the MRO review shall include review of the drug testing chain of custody form to ensure that it is complete and sufficient on its face.

In paragraph (b), a sentence has been added after the first present sentence stating that the MRO shall not be an employee of the laboratory conducting the drug test unless the laboratory establishes a clear separation of functions to prevent any appearance of a conflict of interest, including assuring that the MRO has no responsibility for and is not supervised by or the supervisor of, any persons who have the responsibility for the drug testing or quality control operations of the laboratory. Later in this paragraph, clarifying amendments have been made to the sentence beginning "This action" to say that the action in question includes "conducting a medical interview with the individual" and may also include review of the individual's medical history or review of any other relevant biomedical factors.

Paragraph (c) has been amended by adding the words "for an individual" after the words "positive test result" in the first sentence. New language has been added following the first sentence. It says that the MRO shall make all reasonable efforts to contact the employee directly. If the MRO is unable to contact the employee directly after making these efforts, the MRO would contact a representative of the employer and request that the employer direct the employee to contact the MRO as soon as possible. If the employer cannot get hold of the employee within a reasonable time, the employer may place the employee on medical leave or temporary medically unqualified status. If the employer representative does contact the individual, the MRO may declare the test a verified positive if, after five days have passed from a documented contact instructing the employee to talk to the MRO, the employee has not done so. To protect employees, the MRO may reexamine the verification if the employee documents that exigent circumstances prevented the employee from contacting the MRO in time.

A new paragraph (h) has been added after the end of this section concerning

the disclosure of other medical information. It provides that the MRO may disclose medical information learned as part of the testing/verification process only if the MRO concludes that the information concerns use of medications or a medical condition that could result in the employee becoming medically unqualified under applicable DOT rules or which otherwise could adversely effect transportation safety. The MRO would inform the employee, at the start of the verification interview, of the potential disclosure of such information.

Section 40.35 Protection of employee records. A sentence has been added at the end of this section providing that the laboratory shall disclose information related to a positive drug test of an individual to the individual, the employer or the decisionmaker in a lawsuit, grievance or other formal proceeding initiated by or on behalf of the individual and arising from a verified positive drug test (including a challenge to a DOT agency's action concerning an employee; medical certificate, license, or other document).

Section 40.39 Use of DHHS-certified laboratories. The section number for this section has been changed from § 40.41 to § 40.39. The last two sentences of the section, referring to the DHHS certification standards set forth in appendix A, have been deleted, as has the old appendix A itself.

Enforcement Considerations

Although not directly as a part of this rulemaking, a number of persons have raised concerns about the enforcement of the Department's drug testing programs. The six operating administration rules to which part 40 procedures apply are part of existing statutory and regulatory systems. Generally, they will be enforced in the same way as the rest of those systems. For example, FAA and FHWA personnel inspect the equipment and records of the carriers they regulate. If they find rule violations, they may initiate enforcement proceedings and impose civil penalties. The FAA or FHWA personnel would add review of compliance with drug testing requirements to the other checks they make of employers' compliance with safety rules.

During the initial stages of the implementation of the Department's drug testing rules, the Department's focus will be on assisting employers to comply with the regulations, not on penalizing inadvertent or minor errors. At the same time, the Department will not tolerate intentional violations of the rules or deliberate schemes to avoid compliance.

For example, one major industry association has expressed concern that sham consortiums could be created. Such a sham would allow members to claim that covered employees were being tested, but little or no testing would actually take place. If the Department were to determine that such a sham consortium existed, the Department would take all enforcement action possible under its regulations and, since false statements or fraudulent documentation may be involved, refer appropriate cases to Federal law enforcement authorities for possible criminal prosecution.

Regulatory Process Matters

This is not a major rule under Executive Order 12291. It is a significant rule under the Department's Regulatory Policies and Procedures, since it affects several operating administrations and the industries they regulate. The costs of conducting drug testing conforming with these procedures were analyzed in the regulatory evaluations or regulatory impact analyses for the operating administration drug-testing rules. The provisions of this final rule which may affect costs are relatively few. Use of a sealed collection container/specimen bottle is likely to add only marginally to program costs; this is already common practice, in any case. Since the use of a "split sample" is not mandatory, any costs incurred by employers for this purpose are assumed to be voluntary. The elimination of the "batch reporting" requirement may result in marginal savings to labs and employers in reporting costs.

There should be significant saving to larger employers because of reductions in blind testing requirements. The maximum number of blind samples to be submitted per quarter has also been lowered. The costs to employers should be reduced proportionately. Costs will also be lower because of projected reductions in per sample costs (e.g., to $10–20 per sample, according to information from DHHS.

This saving will be offset, to some degree, by adding blind sample requirements for smaller companies. But the low rate of testing for these companies, added to the lower-cost alternatives for blind samples, should mean that individual employers will not face a heavy burden. For example, a trucking company with 50 covered drivers (assuming a 50 percent random testing rate and the replacement of half of its drivers per year) would have to submit only three blind samples every two years, at minimal cost.

This rule will affect small entities in all the industries covered by DOT operating administration drug rules. The basic small entity impacts of each rule have been considered as part of the operating administrations' rulemakings. The rule to which these amendments apply includes steps to reduce small entity impacts in such areas as inspections, submission of blind samples, and permanent log books. Consequently, the Department certifies that 49 CFR part 40 will not have a significant economic impact on a substantial number of small entities.

The Department has considered the federalism implications of this rule under Executive Order 12612. The Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment. Federalism implications of individual operating administrations' drug rules are discussed in those rulemaking documents.

The reporting and recordkeeping requirements referenced in this regulation have been submitted for Paperwork Reduction Act approval to the Office of Management and Budget by the respective DOT operating administrations in connection with their own drug rules. This is because it is the operating administration rules, rather than this rule, that actually impose the requirements on regulated parties. However, the Office of the Secretary is seeking OMB approval under the Paperwork Reduction Act for the revised form. A **Federal Register** notice will be published when Paperwork Act Approval is obtained.

Issued this 27th day of November 1989 at Washington, DC.

Samuel K. Skinner,

Secretary of Transportation.

List of Subjects in 49 CFR Part 40

Controlled substances, Transportation.

For the reasons set forth in the preamble, the Department of Transportation makes the following amendments in title 49, Code of Federal Regulations, part 40:

1. The authority citation for 49 CFR part 40 is revised to read as follows:

Authority: 49 U.S.C. 102, 301, 322.

2. 49 CFR part 40 is revised to read as follows:

PART 40—PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG TESTING PROGRAMS

Sec.

Authority: 49 U.S.C. 102, 301, 322.

§ 40.1 Applicability.

This part applies to transportation employers (including self-employed individuals) conducting drug urine testing programs pursuant to regulations issued by agencies of the Department of Transportation and to such transportation employers' officers, employees, agents and contractors, to the extent and in the manner provided in DOT agency regulations.

§ 40.3 Definitions.

For purposes of this part the following definitions apply:

Aliquot. A portion of a specimen used for testing.

Blind sample or blind performance test specimen. A urine specimen submitted to a laboratory for quality control testing purposes, with a fictitious identifier, so that the laboratory cannot distinguish it from employee specimens, and which is spiked with known quantities of specific drugs or which is blank, containing no drugs.

Chain of custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an appropriate drug testing custody form (see § 40.23(a)) be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account(s) for the sample or sample aliquots within the laboratory.

Collection container. A container into which the employee urinates to provide the urine sample used for a drug test.

Collection site. A place designated by the employer where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection site person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals.

Confirmatory test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (Gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

DHHS. The Department of Health and Human Services or any designee of the Secretary, Department of Health and Human Services.

DOT agency. An agency (or "operating administration") of the United States Department of Transportation administering regulations requiring compliance with this part, including the United States Coast Guard, the Federal Aviation Administration, the Federal Railroad Administration, the Federal Highway Administration, the Urban Mass Transportation Administration and the Research and Special Programs Administration.

Employee. An individual designated in a DOT agency regulation as subject to drug urine testing and the donor of a specimen under this part. As used in this part "employee" includes an applicant for employment. "Employee" and "individual" or "individual to be tested" have the same meaning for purposes of this part.

Employer. An entity employing one or more employees that is subject to DOT agency regulations requiring compliance with this part. As used in this part, "employer" includes an industry consortium or joint enterprise comprised of two or more employing entities, but no single employing entity is relieved of its responsibility for compliance with this part by virtue of participation in such a consortium or joint enterprise.

Initial test (also known as screening test). An immunoassay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer (MRO). A licensed physician responsible for receiving laboratory results generated by an employer's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's confirmed positive test result together with his or her medical history and any other relevant biomedical information.

Secretary. The Secretary of Transportation or the Secretary's designee.

Shipping container. A container capable of being secured with a tamper proof seal that is used for transfer of one or more specimen bottle(s) and associated documentation from the collection site to the laboratory.

Specimen bottle. The bottle which, after being labeled and sealed according to the procedures in this part, is used to transmit a urine sample to the laboratory.

§§ 40.5–40.19 [Reserved]

§ 40.21 The drugs.

(a) DOT agency drug testing programs require that employers test for marijuana, cocaine, opiates, amphetamines and phencyclidine.

(b) An employer may include in its testing protocols other controlled substances or alcohol only pursuant to a DOT agency approval, if testing for those substances is authorized under agency regulations and if the DHHS has established an approved testing protocol and positive threshold for each such substance.

(c) Urine specimens collected under DOT agency regulations requiring compliance with this part may only be used to test for controlled substances designated or approved for testing as described in this section and shall not be used to conduct any other analysis or test unless otherwise specifically authorized by DOT agency regulations.

(d) This section does not prohibit procedures reasonably incident to analysis of the specimen for controlled substances (e.g., determination of pH or tests for specific gravity, creatinine concentration or presence of adulterants).

§ 40.23 Preparation for testing.

The employer and certified laboratory shall develop and maintain a clear and well-documented procedure for collection, shipment, and accessioning of urine specimens under this part. Such a procedure shall include, at a minimum, the following:

(a) Utilization of a standard drug testing custody and control form (carbonless manifold). The form shall be a multiple-part, carbonless record form with an original (copy 1), and a "second original" (copy 2), both of which shall accompany the specimen to the laboratory. Copies shall be provided for the Medical Review Officer (copy 3, to go directly to the MRO), the donor (copy

4), the collector (copy 5), and the employer representative (copy 6). If the employer desires to exercise the split sample option, then an additional copy of the urine custody and control form is required. This copy (copy 7) shall be the "split specimen original," and is to accompany the split specimen to the same lab, a second lab, or an employer storage site. There must be a positive link established between the first specimen and the split specimen through the specimen identification number; the split specimen identification number shall be an obvious derivative of the first specimen identification number. The form should be a permanent record on which identifying data on the donor, and on the specimen collection and transfer process, is retained. The form shall be constructed to display, at a minimum, the following elements, which shall appear on its respective parts as indicated:

(1) The following information shall appear on all parts of the form:

(i) A preprinted specimen identification number, which shall be unique to the particular collection. If the split sample option is exercised, the preprinted specimen identification number for split specimen shall be an obvious derivative of the first specimen; e.g., first specimen identification number suffixed "A," split specimen suffixed "B."

(ii) A block specifying the donor's employee identification number or Social Security number, which shall be entered by the collector.

(iii) A block specifying the employer's name, address, and identification number.

(iv) A block specifying the Medical Review Officer's name and address.

(v) Specification for which drugs the specimen identified by this form will be tested.

(vi) Specification for the reason for which this test conducted (preemployment, random, etc.), which shall be entered by the collector.

(vii) A block specifying whether or not the collector read the temperature within 4 minutes, and then notation, by the collector, that the temperature of specimen just read is within the range of 32.5–37.7C/90.5–99.8F; if not within the acceptable range, an area is provided to record the actual temperature.

(viii) A chain-of-custody block providing areas to enter the following information for each transfer of possession: Purpose of change; released by (signature/print name); received by (signature/print name); date. The words "Provide specimen for testing" and "DONOR" shall be preprinted in the initial spaces.

(ix) Information to be completed by the collector: Collector's name; date of collection; location of the collection site; a space for remarks at which unusual circumstances may be described; notation as to whether or not the split specimen was taken in accordance with Federal requirements *if* the option to offer the split specimen was exercised by the employer; and a certification statement as set forth below and a signature block with date which shall be completed by the collector:

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

(2) Information to be provided by the laboratory after analysis, which shall appear on parts 1, 2 and 7 (if applicable) of the form only: Accession number; laboratory name; address; a space for remarks; specimen results; and certification statement as set forth below, together with spaces to enter the printed name and signature of the certifying laboratory official and date:

I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen.

(3) A block to be completed by the Medical Review Officer (MRO), after the review of the specimen, which shall appear on parts 1, 2 and 7 (if applicable) of the form only, provides for the MRO's name, address, and certification, to read as follows, together with spaces for signature and date:

I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My final determination/verification is:

(4) Information to be provided by the donor, which shall appear on parts 3 through 6 of the form only: Donor name (printed); daytime phone number; date of birth; and certification statement as set forth below, together with a signature block with date which shall be completed by the donor.

I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

(5) A statement to the donor which shall appear only on parts 3 and 4 of the form, as follows:

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 4—Donor) of this form—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE YOUR COPY WITH YOU.

A form meeting the requirements of this paragraph is displayed at appendix A to this part.

(6) The drug testing custody and control form may include such additional information as may be required for billing or other legitimate purposes necessary to the collection, provided that personal identifying information on the donor (other than the social security number) may not be provided to the laboratory. Donor medical information may appear only on the copy provided to the donor.

(b)(1) Use of a clean, single-use specimen bottle that is securely wrapped until filled with the specimen. A clean, single-use collection container (e.g., disposable cup or sterile urinal) that is securely wrapped until used may also be employed. *If urination is directly into the specimen bottle,* the specimen bottle shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided. *If a separate collection container is used for urination,* the collection container shall be provided to the employee still sealed in its wrapper or shall be unwrapped in the employee's presence immediately prior to its being provided; and the collection site person shall unwrap the specimen bottle in the presence of the employee at the time the urine specimen is presented.

(2) Use of a tamperproof sealing system, designed in a manner such to ensure against undetected opening. The specimen bottle shall be identified with a unique identifying number identical to that appearing on the urine custody and control form, and space shall be provided to initial the bottle affirming its identity. For purposes of clarity, this part assumes use of a system made up of one or more preprinted labels and seals (or a unitary label/seal), but use of other, equally effective technologies is authorized.

(c) Use of a shipping container in which the specimen and associated paperwork may be transferred and which can be sealed and initialled to prevent undetected tampering. In the split specimen option is exercised, the split specimen and associated paperwork shall be sealed in a shipping (or storage) container and initialled to prevent undetected tampering.

(d) Written procedures, instructions and training shall be provided as follows:

(1) Employer collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and is to avoid any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(2) A collection site person shall have successfully completed training to carry out this function or shall be a licensed medical professional or technician who is provided instructions for collection under this part and certifies completion as required in this part

(i) A non-medical collection site person shall receive training in compliance with this part and shall demonstrate proficiency in the application of this part prior to serving as a collection site person. A medical professional, technologist or technician licensed or otherwise approved to practice in the jurisdiction in which the collection takes place is not required to receive such training if that person is provided instructions described in this part and performs collections in accordance with those instructions.

(ii) Collection site persons shall be provided with detailed, clear instructions on the collection of specimens in compliance with this part. Employer representatives and donors subject to testing shall also be provided standard written instructions setting forth their responsibilities.

(3) Unless it is impracticable for any other individual to perform this function, a direct supervisor of an employee shall not serve as the collection site person for a test of the employee. If the rules of a DOT agency are more stringent than this provision regarding the use of supervisors as collection site personnel, the DOT agency rules shall prevail with respect to testing to which they apply.

(4) In any case where a collection is monitored by non-medical personnel or is directly observed, the collection site person shall be of the same gender as the donor. A collection is monitored for this purpose if the enclosure provides less than complete privacy for the donor (e.g., if a restroom stall is used and the collection site person remains in the restroom, or if the collection site person is expected to listen for use of unsecured sources of water.)

§ 40.25 Specimen collection procedures.

(a) *Designation of collection site.* (1) Each employer drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities and supervision to provide for the collection, security, temporary storage, and shipping or transportation of uring specimens to a certified drug testing laboratory. An independent medical facility may also be utilized as a collection site provided the other applicable requirements of this part are met.

(2) A designated collection site may be any suitable location where a specimen can be collected under conditions set forth in this part, including a properly equipped mobile facility. A designated collection site shall be a location having an enclosure within which private urination can occur, a toilet for completion of urination (unless a single-use collector is used with sufficient capacity to contain the void), and a suitable clean surface for writing. The site must also have a source of water for washing hands, which, if practicable, should be external to the enclosure where urination occurs.

(b) *Security.* The purpose of this paragraph is to prevent unauthorized access which could compromise the integrity of the collection process or the specimen.

(1) Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(2) A facility normally used for other purposes, such as a public rest room or hospital examining room, may be secured by visual inspection to ensure other persons are not present and undetected access (e.g., through a rear door not in the view of the collection site person) is not possible. Security during collection may be maintained by effective restriction of access to collection materials and specimens. In the case of a public rest room, the facility must be posted against access during the entire collection procedure to avoid embarrassment to the employee or distraction of the collection site person.

(3) If it is impractical to maintain continuous physical security of a collection site from the time the specimen is presented until the sealed mailer is transferred for shipment, the following minimum procedures shall apply. The specimen shall remain under the direct control of the collection site person from delivery to its being sealed in the mailer. The mailer shall be immediately mailed, maintained in secure storage, or remain until mailed under the personal control of the collection site person.

(c) *Chain of custody.* The chain of custody block of the drug testing custody and control form shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to authorized personnel only.* No unauthorized personnel shall be permitted in any part of the designated collection site where urine specimens are collected or stored. Only the collection site person may handle specimens prior to their securement in the mailing container or monitor or observe specimen collection (under the conditions specified in this part). In order to promote security of specimens, avoid distraction of the collection site person and ensure against any confusion in the identification of specimens, the collection site person shall have only one donor under his or her supervision at any time. For this purpose, a collection procedure is complete when the urine bottle has been sealed and initialled, the drug testing custody and control form has been executed, and the employee has departed the site (or, in the case of an employee who was unable to provide a complete specimen, has entered a waiting area).

(e) *Privacy.* (1) Procedures for collecting urine specimens shall allow individual privacy unless there is a reason to believe that a particular individual may alter or substitute the specimen to be provided, as further described in this paragraph.

(2) For purposes of this part, the following circumstances are the exclusive grounds constituting a reason to believe that the individual may alter or substitute the specimen:

(i) The employee has presented a urine specimen that falls outside the normal temperature range (32.5°–37.7 °C/90.5°–99.8 °F), and

(A) The employee declines to provide a measurement of oral body

temperature, as provided in paragraph (f)(14) of the part; or

(B) Oral body temperature varies by more than 1°C/1.8°F from the temperature of the specimen;

(ii) The last urine specimen provided by the employee (i.e., on a previous occasion) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below .2g/L;

(iii) The collection site person observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (e.g., substitute urine in plain view, blue dye in specimen presented, etc.); or

(iv) The employee has previously been determined to have used a controlled substance without medical authorization and the particular test was being conducted under a DOT agency regulation providing for follow-up testing upon or after return to service.

(3) A higher-level supervisor of the collection site person, or a designated employer representative, shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based upon the circumstances described in subparagraph (2) of this paragraph.

(f) *Integrity and identity of specimen.* Employers shall take precautions to ensure that a urine specimen is not adulterated or diluted during the collection procedure and that information on the urine bottle and on the urine custody and control form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. Where practicable, there shall be no other source of water (e.g., shower or sink) in the enclosure where urination occurs. If there is another source of water in the enclosure it shall be effectively secured or monitored to ensure it is not used as a source for diluting the specimen.

(2) When an individual arrives at the collection site, the collection site person shall ensure that the individual is positively identified as the employee selected for testing (e.g., through presentation of photo identification or identification by the employer's representative). If the individual's identity cannot be established, the collection site person shall not proceed with the collection. If the employee requests, the collection site person shall show his/her identification to the employee.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet. If the employee requests it, the collection site personnel shall provide the employee a receipt for any personal belongings.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collection site person shall provide the individual with a specimen bottle or collection container, if applicable, for this purpose.

(8) The collection site person shall note any unusual behavior or appearance on the urine custody and control form.

(9) In the exceptional event that an employer-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., circumstances require a post-accident test), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10)(i) Upon receiving the specimen from the individual, the collection site person shall determine if it contains at least 60 milliliters of urine. If the individual is unable to provide a 60 milliliters of urine, the collection site person shall direct the individual to drink fluids and, after a reasonable time, again attempt to provide a complete sample using a fresh specimen bottle (and fresh collection container, if employed). The original specimen shall be discarded. If the employee is still unable to provide a complete specimen, the following rules apply:

(A) In the case of a post-accident test or test for reasonable cause (as defined by the DOT agency), the employee shall remain at the collection site and continue to consume reasonable quantities of fluids until the specimen has been provided or until the expiration of a period up to 8 hours from the beginning of the collection procedure.

(B) In the case of a preemployment test, random test, periodic test or other test not for cause (as defined by the DOT agency), the employer may elect to proceed as specified in paragraph (f)(10)(i)(A) of this section (consistent with any applicable restrictions on hours of service) or may elect to discontinue the collection and conduct a subsequent collection at a later time.

(C) If the employee cannot provide a complete sample within the up to 8-hour period or at the subsequent collection, as applicable, then the employer's MRO shall refer the individual for a medical evaluation to develop pertinent information concerning whether the individual's inability to provide a specimen is genuine or constitutes a refusal to provide a specimen. (In preemployment testing, if the employer does not wish to hire the individual, the MRO is not required to make such a referral.) Upon completion of the examination, the MRO shall report his or her conclusions to the employer in writing.

(ii) The employer may, but is not required to, use a "split sample" method of collection.

(A) The donor shall urinate into a collection container, which the collection site person, in the presence of the donor, after determining specimen temperature, pours into two specimen bottles.

(B) The first bottle is to be used for the DOT-mandated test, and 60 ml of urine shall be poured into it. If there is no additional urine available for the second

specimen bottle, the first specimen bottle shall nevertheless be processed for testing.

(C) Up to 60 ml of the remainder of the urine shall be poured into the second specimen bottle.

(D) All requirements of this part shall be followed with respect to both samples, including the requirement that a copy of the chain of custody form accompany each bottle processed under "split sample" procedures.

(E) Any specimen collected under "split sample" procedures must be stored in a secured, refrigerated environment and an appropriate entry made in the chain of custody form.

(F) If the test of the first bottle is positive, the employee may request that the MRO direct that the second bottle be tested in a DHHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the first bottle. The result of this test is transmitted to the MRO without regard to the cutoff values of § 40.29. The MRO shall honor such a request if it is made within 72 hours of the employee's having actual notice that he or she tested positive.

(G) Action required by DOT regulations as the result of a positive drug test (e.g., removal from performing a safety-sensitive function) is not stayed pending the result of the second test.

(H) If the result of the second test is negative, the MRO shall cancel the test.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measure is critical and in no case shall exceed 4 minutes.

(13) A specimen temperature outside the range of 32.5°–37.7 °C/90.5°–99.8 °F constitutes a reason to believe that the individual has altered or substituted the specimen (see paragraph (e)(2)(i) of this section). In such cases, the individual supplying the specimen may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the urine custody and control form.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual has altered or substituted the specimen as described in paragraph (e)(2) (i) or (iii) of this section, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. As provided below, the specimen shall be sealed (by placement of a tamperproof seal over the bottle cap and down the sides of the bottle) and labeled in the presence of the employee. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual being tested shall be present at the same time during procedures outlined in paragraphs (f)(19)–(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the employer. If separate from the label, the tamperproof seal shall also be applied.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the drug testing custody and control form all information identifying the specimen. The collection site person shall sign the drug testing custody and control form certifying that the collection was accomplished according to the applicable Federal requirements.

(22)(i) The individual shall be asked to read and sign a statement on the drug testing custody and control form certifying that the specimen identified as having been collected from him or her is in fact the specimen he or she provided.

(ii) When specified by DOT agency regulation or required by the collection site (other than an employer site) or by the laboratory, the employee may be required to sign a consent or release form authorizing the collection of the specimen, analysis of the specimen for designated controlled substances, and release of the results to the employer. The employee may not be required to waive liability with respect to negligence on the part of any person participating in the collection, handling or analysis of the specimen or to indemnify any person for the negligence of others.

(23) The collection site person shall complete the chain of custody portion of the drug testing custody and control form to indicate receipt of the specimen from the employee and shall certify proper completion of the collection.

(24) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, the collection site person shall ensure that it is appropriately safeguarded during temporary storage.

(25)(i) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station momentarily, the collection site person shall take the specimen and drug testing custody and control form with him or her or shall secure them. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, he or she shall package the specimen for mailing before leaving the site.

(ii) The collection site person shall not leave the collection site in the interval between presentation of the specimen by the employee and securement of the sample with an identifying label bearing the employee's specimen identification number (shown on the urine custody and control form) and seal initialed by the employee. If it becomes necessary for the collection site person to leave the site during this interval, the collection shall be nullified and (at the election of the employer) a new collection begun.

(g) *Collection control.* To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled.

(h) *Transportation to laboratory.* Collection site personnel shall arrange to ship the collected specimen to the drug testing laboratory. The specimens shall be placed in shipping containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes and/or padded mailers); and those containers shall be securely

sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site person shall sign and enter the date specimens were sealed in the shipping containers for shipment. The collection site person shall ensure that the chain of custody documentation is attached or enclosed in each container sealed for shipment to the drug testing laboratory.

(i) *Failure to cooperate.* If the employee refuses to cooperate with the collection process, the collection site person shall inform the employer representative and shall document the non-cooperation on the drug testing custody and control form.

(j) *Employee requiring medical attention.* If the sample is being collected from an employee in need of medical attention (e.g., as part of a post-accident test given in an emergency medical facility), necessary medical attention shall not be delayed in order to collect the specimen.

(k) *Use of chain of custody forms.* A chain of custody form (and a laboratory internal chain of custody document, where applicable) shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on the form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

§ 40.27 Laboratory personnel.

(a) *Day-to-day management.* (1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by a State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraph (a)(2) (i), (ii), or (iii) of this section, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in § 40.29(n)(1).)

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) *Test validation.* The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) *Day-to-day operations and supervision of analysts.* The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience, certification or license if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

§ 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory process or to areas where records are stored. Access to these

secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles generally shall be retained within the laboratory's accession area until all analyses have been completed. Aliquots and the laboratory's chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests.

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) *Initial test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test cutoff levels (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	*300
Phencyclidine	25
Amphetamines	1,000

*25 ng/ml if immunoassay specific for free morphine.

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(f) *Confirmatory test.* (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff levels listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations that exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

	Confirmatory test cutoff levels (ng/ml)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	150
Opiates:	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(g) *Reporting results.* (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, the specimen number assigned by the employer, and the drug testing laboratory specimen identification number (accession number).

(2) The laboratory shall report as negative all specimens that are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The MRO shall report whether the test is positive or negative, and may report the drug(s) for which there was a positive test, but shall not disclose the quantitation of test results to the employer. *Provided,* that the MRO may reveal the quantitation of a positive test result to the employer, the employee, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the employee and arising from a verified positive drug test.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the drug testing custody and control form (part 2), which, in the case of a report positive for drug use, shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(6) The laboratory shall provide to the employer official responsible for coordination of the drug testing program a monthly statistical summary of

urinalysis testing of the employer's employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:
(A) Number of specimens received;
(B) Number of specimens reported out; and
(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamine

(ii) Confirmatory Testing:
(A) Number of specimens received for confirmation;
(B) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

Monthly reports shall not include data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary, in order to prevent the disclosure of such data, the laboratory shall not send a report until data are sufficiently aggregated to make such an inference unlikely. In any month in which a report is withheld for this reason, the laboratory will so inform the employer in writing.

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-term storage.* Long-term frozen storage (−20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive, in their original labeled specimen bottles. Within this 1-year period, an employer (or other person designated in a DOT agency regulation) may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens known to be under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, and the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor.

(k) *Laboratory facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensing requirements.

(2) Laboratories certified in accordance with DHHS Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserves the right to inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agent) to conduct unannounced inspections.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2 year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall maintain documents for any specimen known to be under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of methods, cutoff values, mechanisms for reporting results, controls criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these

procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

§ 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody security and reporting of results, initial and confirmatory testing and validation of analytical procedures. Quality assurance procedures shall be designed, implemented and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory quality control requirements for initial tests.* Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level.

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure the carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) *Laboratory quality control requirements for confirmation tests.* Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level. The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) *Employer blind performance test procedures.*

(1) Each employer covered by DOT agency drug testing regulations shall use blind testing quality control procedures as provided in this paragraph.

(2) Each employer shall submit three blind performance test specimens for each 100 employee specimens it submits, up to a maximum of 100 blind performance test specimens submitted per quarter. A DOT agency may increase this per quarter maximum number of samples if doing so is necessary to ensure adequate quality control of employers or consortiums with very large numbers of employees.

(3) For employers with 2000 or more covered employees, approximately 80 percent of the blind performance test samples shall be blank (i.e., containing no drug or otherwise as approved by a DOT agency) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the employer is testing. This paragraph shall not be construed to prohibit spiking of other (potentially interfering) compounds, as technically appropriate, in order to verify the specificity of a particular assay.

(4) Employers with fewer than 2000 covered employees may submit blind performance test specimens as provided in paragraph (d)(3) of this section. Such employers may also submit only blank samples or may submit two separately labeled portions of a specimen from the same non-covered employee.

(5) Consortiums shall be responsible for the submission of blind samples on behalf of their members. The blind sampling rate shall apply to the total number of samples submitted by the consortium.

(6) The DOT agency concerned shall investigate, or shall refer to DHHS for investigation, any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be made of the investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individual responsible for the day-to-day management and operation of the drug testing laboratory. Then the DOT agency shall send the document to the employer as a report of the unsatisfactory performance testing incident. The DOT agency shall ensure notification of the finding to DHHS.

(7) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the employer shall promptly notify the DOT agency concerned. The DOT agency and the employer shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future, and, if there is reason to believe the error could have been systemic, the DOT agency may also require review and reanalysis of previously run specimens.

(8) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the employer shall instruct the laboratory to submit all quality control data from the batch of specimens which included the false positive specimen to the DOT agency concerned. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The DOT agency concerned may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. Based on information provided by the DOT agency, DHHS has the option of revoking or suspending the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

§ 40.33 Reporting and review of results.

(a) *Medical review officer shall review confirmed positive results.* (1) An essential part of the drug testing program is the final review of confirmed positive results from the laboratory. A positive test result does not automatically identify an employee/applicant as having used drugs in violation of a DOT agency regulation.

An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer (MRO) prior to the transmission of the results to employer administrative officials. The MRO review shall include review of the chain of custody to ensure that it is complete and sufficient on its face.

(2) The duties of the MRO with respect to negative results are purely administrative.

(b) *Medical review officer—qualifications and responsibilities.* (1) The MRO shall be a licensed physician with knowledge of substance abuse disorders and may be an employee of a transportation employer or a private physician retained for this purpose.

(2) The MRO shall not be an employee of the laboratory conducting the drug test unless the laboratory establishes a clear separation of functions to prevent any appearance of a conflict of interest, including assuring that the MRO has no responsibility for, and is not supervised by or the supervisor of, any persons who have responsibility for the drug testing or quality control operations of the laboratory.

(3) The role of the MRO is to review and interpret confirmed positive test results obtained through the employer's testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action may include conducting a medical interview and review of the individual's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The MRO shall not, however, consider the results or urine samples that are not obtained or processed in accordance with this part.

(c) *Positive test result.* (1) Prior to making a final decision to verify a positive test result for an individual, the MRO shall give the individual an opportunity to discuss the test result with him or her.

(2) The MRO shall contact the individual directly, on a confidential basis, to determine whether the employee wishes to discuss the test result. A staff person under the MRO's supervision may make the initial contact, and a medically licensed or certified staff person may gather information from the employee. Except as provided in paragraph (c)(5) of this section, the MRO shall talk directly with the employee before verifying a test as positive.

(3) If, after making all reasonable efforts and documenting them, the MRO is unable to reach the individual directly, the MRO shall contact a designated management official who shall direct the individual to contact the MRO as soon as possible. If it becomes necessary to reach the individual through the designated management official, the designated management official shall employ procedures that ensure, to the maximum extent practicable, the requirement that the employee contact the MRO is held in confidence.

(4) If, after making all reasonable efforts, the designated management official is unable to contact the employee, the employer may place the employee on temporary medically unqualified status or medical leave.

(5) The MRO may verify a test as positive without having communicated directly with the employee about the test in three circumstances:

(i) The employee expressly declines the opportunity to discuss the test;

(ii) The designated employer representative has successfully made and documented a contact with the employee and instructed the employee to contact the MRO (see paragraphs (c)(3) and (4) of this section), and more than five days have passed since the date the employee was successfully contacted by the designated employer representative; or

(iii) Other circumstances provided for in DOT agency drug testing regulations.

(6) If a test is verified positive under the circumstances specified in paragraph (c)(5)(ii) of this section, the employee may present to the MRO information documenting that serious illness, injury, or other circumstances unavoidably prevented the employee from timely contacting the MRO. The MRO, on the basis of such information, may reopen the verification, allowing the employee to present information concerning a legitimate explanation for the confirmed positive test. If the MRO concludes that there is a legitimate explanation, the MRO declares the test to be negative.

(7) Following verification of a positive test result, the MRO shall, as provided in the employer's policy, refer the case to the employer's employee assistance or rehabilitation program, if applicable, to the management official empowered to recommend or take administrative action (or the official's designated agent), or both.

(d) *Verification for opiates; review for prescription medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of unauthorized use of any opium, opiate, or opium derivative (e.g., morphine/codeine). (This requirement does not apply if the employer's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) *Reanalysis authorized.* Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified by DHHS. The Medical Review Officer shall authorize a reanalysis of the original sample if requested to do so by the employee within 72 hours of the employee's having received actual notice of the positive test. If the retest is negative, the MRO shall cancel the test.

(f) *Result consistent with legal drug use.* If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO shall report the test result to the employer as negative.

(g) *Result scientifically insufficient.* Additionally, the MRO, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the MRO may request reanalysis of the original sample before making this decision. (The MRO may request that reanalysis as provided in § 40.33(e) be performed by the same laboratory or, that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with the DHHS Guidelines.) The laboratory shall assist in this review process as requested by the MRO by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the employer. The employer shall include in any required annual report to a DOT agency a summary of any negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(h) *Disclosure of information.* Except as provided in this paragraph, the MRO shall not disclose to any third party medical information provided by the individual to the MRO as a part of the testing verification process.

(1) The MRO may disclose such information to the employer, a DOT agency or other Federal safety agency, or a physician responsible for determining the medical qualification of the employee under an applicable DOT agency regulation, as applicable, only if—

(i) An applicable DOT regulation permits or requires such disclosure;

(ii) In the MRO's reasonable medical judgment, the information could result in the employee being determined to be medically unqualified under an applicable DOT agency rule; or

(iii) In the MRO's reasonable medical judgment, in a situation in which there is no DOT agency rule establishing physical qualification standards applicable to the employee, the information indicates that continued performance by the employee of his or her safety-sensitive function could pose a significant safety risk.

(2) Before obtaining medical information from the employee as part of the verification process, the MRO shall inform the employee that information may be disclosed to third parties as provided in this paragraph and the identity of any parties to whom information may be disclosed.

§ 40.35 Protection of employee records.

Employer contracts with laboratories shall require that the laboratory maintain employee test records in confidence, as provided in DOT agency regulations. The contracts shall provide that the laboratory shall disclose information related to a positive drug test of an individual to the individual, the employer, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the individual and arising from a certified positive drug test.

§ 40.37 Individual access to test and laboratory certification results.

Any employee who is the subject of a drug test conducted under this part shall, upon wirtten request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

§ 40.39 Use of DHHS—certified laboratories.

Employers subject to this part shall use only laboratories certified under the DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs," 53 FR 11970, April 11, 1988, and subsequent amendments thereto.

BILLING CODE 4910-62-M

APPENDIX A—DRUG TESTING CUSTODY AND CONTROL FORM

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No.

SPECIMEN IDENTIFICATION No. 123456

PLACE OVER CAP

DATE _____ DONOR'S INITIAL _____

SIGNATURE OF COLLECTOR

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*: _____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII.

SPECIMEN IDENTIFICATION No. 123456

SHIPPING BOX CUSTODY SEAL

FEDERAL REGULATIONS PROHIBIT DISCLOSURE OF THE DONOR'S IDENTITY TO THE LABORATORY. DONOR SHALL COMPLETE INFORMATION IN SECTION VII (COPY 3) ONLY.

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII—*(See Copy 3 of Form)*

VIII. COLLECTOR'S NAME—*PRINT (first, middle, last)* | DATE OF COLLECTION

COLLECTION SITE LOCATION

REMARKS CONCERNING COLLECTION: | Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

TO BE COMPLETED BY THE LABORATORY

IX. I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen. | ACCESSION NO.

LABORATORY | ADDRESS

REMARKS:

(PRINT) Certifying Scientist's Name *(Last, First, Middle)* | Signature of Certifying Scientist | Date

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE SCREENING AND CONFIRMATION CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS* (found only on copies one and two):

☐ NEGATIVE

☐ POSITIVE, for the following:
- ☐ Cannabinoids as Carboxy—THC
- ☐ Cocaine Metabolites as Benzoylecgonine
- ☐ Phencyclidine
- ☐ Opiates
  - ☐ Codeine
  - ☐ Morphine
- ☐ Amphetamines
  - ☐ amphetamines
  - ☐ methamphetamines
- ☐ _____

TO BE COMPLETED BY MEDICAL REVIEW OFFICER

X. I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My final determination/verification is: *(Check one)* _ NEGATIVE ' POSITIVE

SIGNATURE OF MEDICAL REVIEW OFFICER: _____ DATE: _____

COPY 1—ORIGINAL—MUST ACCOMPANY SPECIMEN TO LABORATORY—LABORATORY RETAINS

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No.

SPECIMEN IDENTIFICATION No. 123456

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*:_____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII.

SPECIMEN IDENTIFICATION
No. 123456

FEDERAL REGULATIONS PROHIBIT DISCLOSURE OF THE DONOR'S IDENTITY TO THE LABORATORY.
DONOR SHALL COMPLETE INFORMATION IN SECTION VII (COPY 3) ONLY.

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII-*(See Copy 3 of Form)*

VIII. COLLECTOR'S NAME—*PRINT (first, middle, last)* | DATE OF COLLECTION

COLLECTION SITE LOCATION

REMARKS CONCERNING COLLECTION: | Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

TO BE COMPLETED BY THE LABORATORY

IX. I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen. | ACCESSION NO.

LABORATORY | ADDRESS

REMARKS:

_____ (PRINT) Certifying Scientist's Name *(Last, First, Middle)* _____ Signature of Certifying Scientist _____ Date

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE SCREENING AND CONFIRMATION CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS* (found only on copies one and two):

☐ NEGATIVE

☐ POSITIVE, for the following:
- ☐ Cannabinoids as Carboxy—THC
- ☐ Cocaine Metabolites as Benzoylecgonine
- ☐ Phencyclidine
- ☐ Opiates
  - ☐ Codeine
  - ☐ Morphine
- ☐ Amphetamines
  - ☐ amphetamines
  - ☐ methamphetamines
- ☐ _____

TO BE COMPLETED BY MEDICAL REVIEW OFFICER

X. I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My final determination/verification is: *(Check one)* ☐ NEGATIVE ☐ POSITIVE

SIGNATURE OF MEDICAL REVIEW OFFICER: _____ DATE: _____

COPY 2—2ND ORIGINAL—MUST ACCOMPANY SPECIMEN TO LABORATORY
LAB SENDS TO MRO WITH TEST RESULTS IN SECT. IX

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No.

SPECIMEN IDENTIFICATION No. 123456

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*:_____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII.

NAME *(Last, First, Middle)*	SPECIMEN IDENTIFICATION No. 123456	DAYTIME PHONE NUMBER	DATE OF BIRTH

DONOR CERTIFICATION: I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

SIGNATURE: _____ DATE: _____

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 4—Donor) of this form—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE YOUR COPY WITH YOU.

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII—*(See Copy 3 of Form)*

VIII.

COLLECTOR'S NAME—*PRINT (first, middle, last)*	DATE OF COLLECTION
COLLECTION SITE LOCATION	
REMARKS CONCERNING COLLECTION:	Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

COPY 3—TO MEDICAL REVIEW OFFICER

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No.

SPECIMEN IDENTIFICATION No. 123456

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*:_____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII.

NAME *(Last, First, Middle)*	SPECIMEN IDENTIFICATION No. 123456	DAYTIME PHONE NUMBER	DATE OF BIRTH

DONOR CERTIFICATION: I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

SIGNATURE: _____ DATE: _____

Should the results of the laboratory tests for the specimen identified by this form be confirmed positive, the Medical Review Officer will contact you to ask about prescriptions and over-the-counter medications you may have taken. Therefore, you may want to make a list of those medications as a "memory jogger." THIS LIST IS NOT NECESSARY. If you choose to make a list, do so either on a separate piece of paper or on the back of your copy (Copy 4—Donor) of this form—DO NOT LIST ON THE BACK OF ANY OTHER COPY OF THE FORM. TAKE YOUR COPY WITH YOU.

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII–*(See Copy 3 of Form)*

VIII.

COLLECTOR'S NAME—*PRINT (first, middle, last)*	DATE OF COLLECTION
COLLECTION SITE LOCATION	
REMARKS CONCERNING COLLECTION:	Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

COPY 4—DONOR

BACK-SIDE OF COPY 4—DONOR

LIST PRESCRIPTION DRUGS. ***IT IS NOT REQUIRED, AND IS FOR YOUR USE ONLY.***

_____

_____

_____

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No

SPECIMEN IDENTIFICATION No. 123456

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*:

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*:

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII. NAME *(Last, First, Middle)*

SPECIMEN IDENTIFICATION No. 123456

DONOR CERTIFICATION: I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

SIGNATURE: _____ DATE: _____

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII—*(See Copy 3 of Form)*

VIII. COLLECTOR'S NAME—*PRINT (first, middle, last)*

DATE OF COLLECTION

COLLECTION SITE LOCATION

REMARKS CONCERNING COLLECTION:

Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

COPY 5—COLLECTOR

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No.

SPECIMEN IDENTIFICATION * No. 123456

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*:_____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN
Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE
of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp:* _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII. NAME *(Last, First, Middle)*

SPECIMEN IDENTIFICATION No. 123456

DONOR CERTIFICATION: I certify that I provided my urine specimen to the collector; that the specimen bottle was sealed with a tamper-proof seal in my presence; and that the information provided on this form and on the label affixed to the specimen bottle is correct.

SIGNATURE: _____ DATE: _____

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII–*(See Copy 3 of Form)*

VIII. COLLECTOR'S NAME—*PRINT (first, middle, last)*

DATE OF COLLECTION

COLLECTION SITE LOCATION

REMARKS CONCERNING COLLECTION:

Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

COPY 6—EMPLOYER

Drug Testing Custody and Control Form

EMPLOYEE I.D. No. or SOCIAL SECURITY No. _____

SPECIMEN IDENTIFICATION No. 123456*SPLIT*

PLACE OVER CAP

DATE _____ DONOR'S INITIAL _____

SIGNATURE OF COLLECTOR _____

TO BE COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

I. EMPLOYER NAME, ADDRESS, AND IDENTIFICATION NUMBER

II. MEDICAL REVIEW OFFICER NAME AND ADDRESS

III. INDICATE WHICH DRUGS SPECIMEN IS TO BE TESTED FOR:
☐ Only THC and Cocaine ☐ THC, Cocaine, PCP, Opiates, and Amphetamines ☐ Other *(Specify)*: _____

IV. REASON FOR TEST *(Check one)*
☐ Pre-employment ☐ Random ☐ Post Accident ☐ Periodic Medical ☐ Reasonable Cause ☐ Other *(Specify)*: _____

V. TEMPERATURE OF SPECIMEN Has been read within 4 minutes ☐ Yes ☐ No
TEMPERATURE IS WITHIN RANGE of 32.5°-37.7°C/90.5°-99.8°F ☐ Yes ☐ No—*If NOT, record actual temp*: _____°

TO BE INITIATED BY COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

VI.

PURPOSE OF CHANGE	RELEASED BY—Signature—Print Name	RECEIVED BY—Signature—Print Name	DATE
Provide Specimen for Testing	— DONOR —		

TO BE COMPLETED BY EMPLOYEE OR APPLICANT PROVIDING SPECIMEN

VII.

SPECIMEN IDENTIFICATION
No. 123456*SPLIT*

SHIPPING BOX CUSTODY SEAL

FEDERAL REGULATIONS PROHIBIT DISCLOSURE OF THE DONOR'S IDENTITY TO THE LABORATORY. DONOR SHALL COMPLETE INFORMATION IN SECTION VII (COPY 3) ONLY.

TO BE COMPLETED BY PERSON COLLECTING SPECIMEN *AFTER* DONOR HAS COMPLETED SECTION VII—*(See Copy 3 of Form)*

VIII. COLLECTOR'S NAME—*PRINT (first, middle, last)* | DATE OF COLLECTION

COLLECTION SITE LOCATION

REMARKS CONCERNING COLLECTION: | Split sample collected in accordance with applicable Federal requirements. ☐ Yes ☐ No

I certify that the specimen identified on this form is the specimen presented to me by the donor providing the certification on Copy 3 of this form, that it bears the same identification number as that set forth above, and that it has been collected, labelled and sealed as in accordance with applicable Federal requirements.

SIGNATURE OF COLLECTOR: _____

TO BE COMPLETED BY THE LABORATORY

IX. I certify that the specimen identified by this accession number is the same specimen that bears the identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with applicable Federal requirements, and that the results set forth below are for that specimen. | ACCESSION NO.

LABORATORY | ADDRESS

REMARKS:

_____ (PRINT) Certifying Scientist's Name *(Last, First, Middle)* _____ Signature of Certifying Scientist _____ Date

THE RESULTS FOR THE ABOVE IDENTIFIED SPECIMEN ARE IN ACCORDANCE WITH THE APPLICABLE SCREENING AND CONFIRMATION CUTOFF LEVELS ESTABLISHED BY THE HHS *MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS* (found only on copies one and two):

☐ NEGATIVE ☐ POSITIVE, for the following:
- ☐ Cannabinoids as Carboxy—THC
- ☐ Cocaine Metabolites as Benzoylecgonine
- ☐ Phencyclidine
- ☐ Opiates
  - ☐ Codeine
  - ☐ Morphine
- ☐ Amphetamines
  - ☐ amphetamines
  - ☐ methamphetamines
- ☐ _____

TO BE COMPLETED BY MEDICAL REVIEW OFFICER

X. I have reviewed the laboratory results for the specimen identified by this form in accordance with applicable Federal requirements. My final determination/verification is: *(Check one)* ☐ NEGATIVE ☐ POSITIVE

SIGNATURE OF MEDICAL REVIEW OFFICER: _____ DATE: _____

COPY 7—SPLIT SPECIMEN ORIGINAL—MUST ACCOMPANY SPLIT SPECIMEN TO LABORATORY—LABORATORY RETAINS

[FR Doc. 89-28061 Filed 11-28-89; 10:27 am]

BILLING CODE 4910-62-C

49 CFR Part 40

Announcement of Conferences on DOT-Required Drug Testing

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of conferences.

SUMMARY: The Department of Transportation is sponsoring a series of conferences on Implementing Programs for a Drug-Free Transportation System. This notice concerns the dates, locations, agenda, and registration information for these conferences.

DATES: Conferences are scheduled for the following dates in the following cities:

December 7–8, 1989—Washington, DC.
December 19–20, 1989—Los Angeles, California
January 4–5, 1990—New Orleans, Louisiana
January 18–19—Chicago, Illinois
January 30–31, 1990—Boston, Massachusetts
February 7–8, 1990—Denver, Colorado
February 22–23—Dallas, Texas

FOR FURTHER INFORMATION CONTACT: Donna Smith, Drug Awareness and Education Division, Office of Personnel, Department of Transportation, 400 7th Street, SW., Room 9103, Washington, DC 20590. (202–366–6000). *(See supplementary information for phone number and address of contact for conference registration.)*

SUPPLEMENTARY INFORMATION: In November 1988, the Department of Transportation published regulations requiring drug testing programs in the aviation, maritime, railroad, mass transit, pipeline, and motor carrier industries. Employers in these industries must begin drug testing between December 1989 and December 1990. The Department is pleased that those who are responsible for transportation safety are responding positively to the challenge of implementing this significant and complex program.

As we approach the starting dates for drug testing, it is important for DOT, industry, and other concerned parties to work together to implement these requirements effectively. To this end, the Department is sponsoring a series of conferences, at the times and places listed above, to examine the issues surrounding drug testing and methods to implement drug programs in the transportation industries in accordance with DOT regulations.

The conferences are designed to provide a forum for discussing the rules and how to implement them. Participants will be able to discuss implementation issues, firsthand, with DOT staff responsible for carrying out the regulations.

Each conference will be one and one half days in length. The first day will include an overview of DOT drug testing regulations, an introduction to 49 CFR part 40 (the Department's Drug Testing Procedures rule, a revision of which is being published in today's **Federal Register**; detailed discussion of such issues under part 40 as collection procedures, the chain of custody form, the testing process, quality control measures, and the role of the medical review officer; and the drug awareness and training requirements of the DOT rules. The second day (a half-day) will feature industry break-out sessions, in which employers in each industry will meet with DOT operating administration staff to discuss implementation issues of particular interest to that industry.

Conference participation will be limited to 300 at each site. Based on the number of responses received, the number of participants from a particular organization may be limited. The conference registration fee will be $50 per person. Attendees will be responsible for their own hotel reservations and charges. The hotels at which each conference will be held will be announced at a later date.

For registration materials and information, you should contact the Department's consultant who is administering the conferences, Ricard International Incorporated (RII), 1010 Wayne Avenue, Silver Spring, Maryland 20910. Contact persons at RII are John Smith, Loraine Price, and Sonny Bloom. RII phone numbers are 301–589–6248 (voice) and 301–565–5112 (fax).

Issued this 28th day of November, 1989, at Washington, DC.

Melissa J. Allen,
Deputy Assistant Secretary for Administration.

[FR Doc. 89–28229 Filed 11–30–89; 8:45 am]
BILLING CODE 4910–62–M